Filed pursuant to Rule 424(b)(4)
Registration No. 333-230045

**Prospectus**

# *6,000,000 Shares*


## *Common Stock*

This is an initial public offering of shares of common stock of Silk Road Medical, Inc.

We are offering 6,000,000 shares of common stock. This is our initial public offering and no public market currently exists for our common stock. The initial public offering price is $20.00 per share.

Our common stock has been approved for quotation on The Nasdaq Global Market under the symbol "SILK."

*We are an "emerging growth company" and a "smaller reporting company" as defined under the federal securities laws and, as such, may elect to comply with certain reduced public company reporting requirements for future filings. Investing in our common stock involves a high degree of risk. Please see the section entitled "Risk Factors" starting on page 13 to read about risks you should consider carefully before buying shares of our common stock.*

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense**.

| | Per Share | Total |
|---|---|---|
| Initial Public Offering Price | $ 20.00 | $ 120,000,000 |
| Underwriting Discounts and Commissions[(1)] | $ 1.40 | $ 8,400,000 |
| Proceeds, before expenses, to us | $ 18.60 | $ 111,600,000 |

(1) See the section titled "Underwriting" for a description of the underwriting discounts and commissions and offering expenses.

The selling stockholders have granted the underwriters an option exercisable for 30 days after the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of 900,000 shares from the selling stockholders at the public offering price less underwriting discounts and commissions. We will not receive any proceeds from the sale of the shares by the selling stockholders.

The underwriters expect to deliver the shares on or about April 8, 2019.

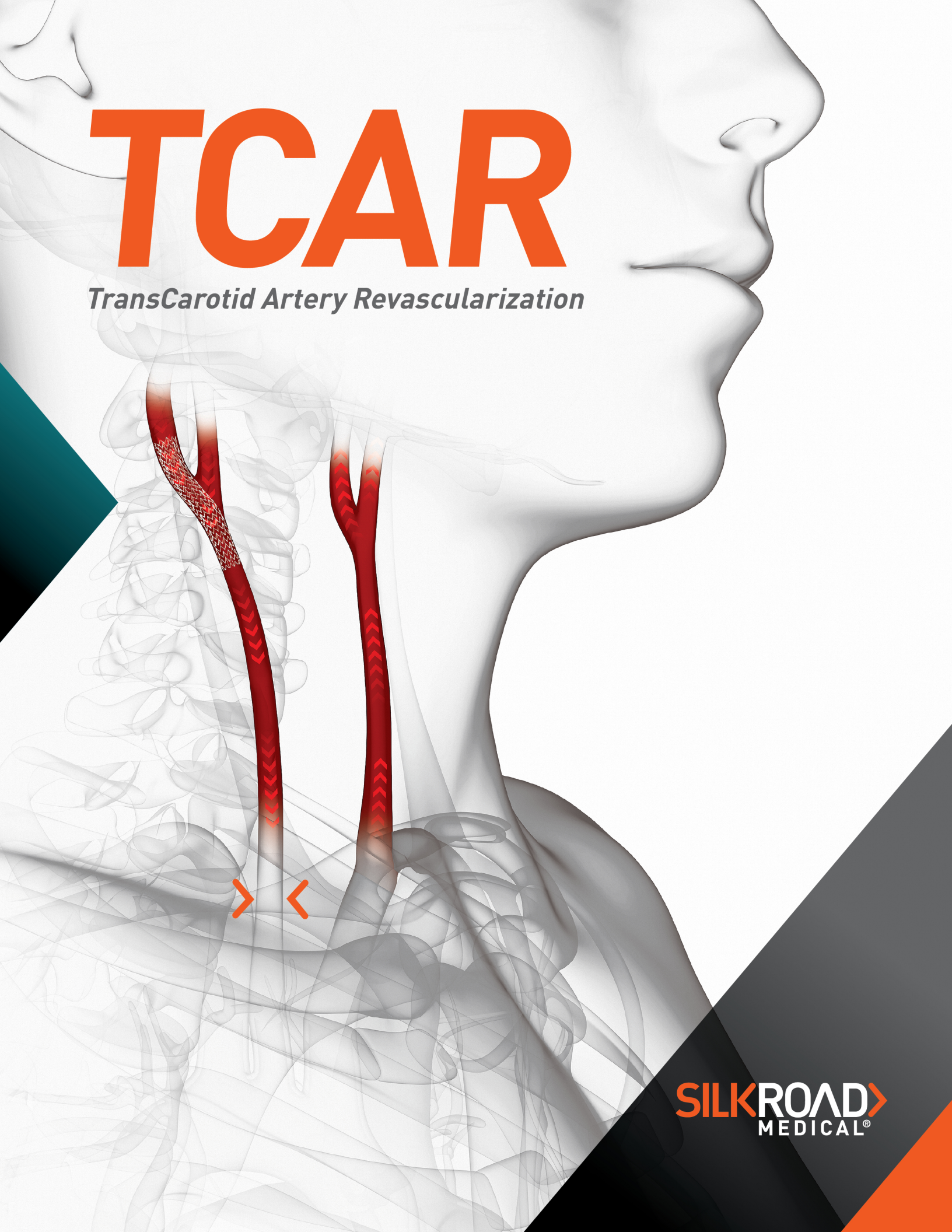
**J.P. Morgan** **BofA Merrill Lynch**

**BMO Capital Markets** **Stifel**

The date of this prospectus is April 3, 2019.

# TCAR

*TransCarotid Artery Revascularization*



SILKROAD MEDICAL®

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**Through and including April 28, 2019 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.**

Neither we, the selling stockholders, nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We, the selling stockholders, and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is accurate only as of the date of this prospectus regardless of the time of delivery of this prospectus or of any sale of our common stock.

For investors outside the United States: Neither we, the selling stockholders, nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus and any free writing prospectus related to this offering must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock and the distribution of this prospectus and any such free writing prospectus outside of the United States.

# PROSPECTUS SUMMARY

*This summary highlights selected information contained in greater detail elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read the entire prospectus, including the sections entitled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and related notes thereto included elsewhere in this prospectus. As used in this prospectus, references to "we," "our," "us," "the company" and "Silk Road Medical" refer to Silk Road Medical, Inc. and, where appropriate, its wholly-owned subsidiaries unless the context requires otherwise.*

## Overview

We are a medical device company focused on reducing the risk of stroke and its devastating impact. We believe a key to stroke prevention is minimally-invasive and technologically advanced intervention to safely and effectively treat carotid artery disease, one of the leading causes of stroke. We have pioneered a new approach for the treatment of carotid artery disease called transcarotid artery revascularization, or TCAR, which we seek to establish as the standard of care.

TCAR relies on two novel concepts - minimally-invasive direct carotid access in the neck and high-rate blood flow reversal during the procedure to protect the brain - and combines the benefits of innovative endovascular techniques with fundamental surgical principles. TCAR using our portfolio of products has been clinically demonstrated to reduce the upfront morbidity and mortality profile of current treatment alternatives while providing a reduction in long-term stroke risk. We are the first and only company to obtain FDA approvals, secure specific Medicare reimbursement coverage, and commercialize products engineered and indicated for use in TCAR. As of December 31, 2018, more than 7,750 TCAR procedures have been performed globally, including more than 4,600 in 2018.

Carotid artery disease is the progressive buildup of plaque causing narrowing of the arteries in the front of the neck, which supply blood flow to the brain. Plaque can embolize, or break away from the arterial wall, travel toward the brain and interrupt critical blood supply, leading to an ischemic stroke. Carotid artery disease is one of the leading causes of stroke, and stroke is one of the most catastrophic, debilitating and costly conditions worldwide. We believe the best way to mitigate the mortality, morbidity and cost burden of stroke is to prevent strokes in the first place. Clinical evidence has demonstrated that with proper diagnosis and treatment, stroke due to carotid artery disease is mostly preventable. We believe there were approximately 4.3 million people with carotid artery disease in the United States in 2018, with an estimated 427,000 new diagnoses in 2018, and that existing treatment options have substantial safety and effectiveness limitations.

The goal of treating carotid artery disease is to prevent a future stroke. When intervention beyond medical management is warranted, the current standard of care for reduction in stroke risk is an invasive carotid revascularization procedure called carotid endarterectomy, or CEA. While generally effective at reducing the risk of stroke over the long term, large randomized clinical trials have demonstrated that CEA is associated with an upfront risk of adverse events such as cranial nerve injury, heart attack, wound complications and even stroke and death. To address the invasiveness of CEA, transfemoral carotid artery stenting, or CAS, was first performed in 1993 and further developed to offer a minimally-invasive, catheter-based alternative for physicians and their patients. Despite reducing the risk of certain adverse events associated with CEA, multiple randomized clinical trials and other studies have shown that CAS, relative to CEA, often results in an almost two-fold increase in stroke within the first 30 days following treatment, which we believe is due to inadequate protection of the brain. We believe this represents an unacceptable trade-off relative to the current standard of care of CEA and has limited the adoption of CAS. As a result, we believe there remains an unmet clinical need to offer patients a reduction in 30-day stroke risk with fewer procedure-related adverse events, while maintaining a reduction in long-term stroke risk beyond the first 30 days.

TCAR is a minimally-invasive solution that addresses the morbidity of CEA and the 30-day stroke risk of CAS while providing a reduction in long-term stroke risk. TCAR starts with a small incision in the neck slightly above the collarbone, otherwise known as transcarotid access, through which our ENROUTE Transcarotid Stent System, or ENROUTE stent, is placed during a period of temporary high-rate blood flow reversal that is enabled by our ENROUTE Transcarotid Neuroprotection System, or ENROUTE NPS. Blood flow reversal directs embolic debris that could cause a stroke away from the brain during the procedure, while the stent braces the plaque and prevents embolization to afford a reduction in long-term stroke risk. We believe that by meeting the standard of brain protection afforded by CEA, while providing benefits commensurate with an endovascular, minimally-invasive approach, TCAR will become the preferred alternative for carotid revascularization.

Based on the estimated 427,000 new carotid artery disease diagnoses in the United States in 2018, we believe a total annual U.S. market opportunity of approximately $2.6 billion exists for our portfolio of TCAR products. We are currently focused on penetrating and converting carotid revascularization procedures to TCAR. There were approximately 168,000 carotid revascularization procedures performed in 2018, which we estimate to be a market conversion opportunity greater than $1.0 billion. In 2018, physicians performed over 4,500 TCAR procedures in the United States using our products, representing approximately 1% of annual diagnoses of carotid artery disease in the United States.

The safety, effectiveness and clinical advantages of TCAR have been demonstrated in multiple clinical trials, post-market studies and registries that have evaluated outcomes in more than 3,500 patients in the United States and Europe to date. The results of our U.S. pivotal trial, ROADSTER, reflect the lowest reported 30-day stroke rate for any prospective, multi-center clinical trial of carotid stenting of which we are aware. In a recent contemporaneous comparative analysis, TCAR demonstrated comparable rates of in-hospital stroke and death relative to CEA despite treating a sicker, older patient population. TCAR patients also had a ten-fold reduction in risk of cranial nerve injury, spent less time in the operating room and were less likely to have a hospital stay greater than one day. When compared to CAS, TCAR demonstrated significantly lower rates of in-hospital stroke and death.

We currently market and sell our portfolio of TCAR products in the United States through a direct sales organization. Our ENROUTE NPS and ENROUTE stent have obtained CE Mark approval, allowing us to commercialize in Europe in the future. We also intend to pursue regulatory clearances in China, Japan, and other select international markets.

TCAR is reimbursed based on established current procedural technology, or CPT, codes and International Classification of Diseases, or ICD-10, codes related to carotid stenting that track to Medicare Severity Diagnosis Related Group, or MS-DRG, classifications. In September 2016, the Centers for Medicare and Medicaid Services, or CMS, made TCAR available for coverage in symptomatic and asymptomatic patients at high risk for adverse events from CEA treated at facilities participating in the TCAR Surveillance Project, an ongoing open-ended registry sponsored by the Society for Vascular Surgery through the Vascular Quality Initiative, or VQI.

We have experienced considerable growth since we began commercializing our products in the United States in late 2015. Our revenue increased from $14.3 million for the year ended December 31, 2017 to $34.6 million for the year ended December 31, 2018, representing growth of 142%, and our net losses were $19.4 million and $37.6 million for the years ended December 31, 2017 and December 31, 2018, respectively. Our accumulated deficit was $139.1 million as of December 31, 2018.

We believe the continued growth of our company will be driven by the following competitive strengths:

- Paradigm-shifting transcarotid access and flow reversal technologies;
- Compelling body of clinical and economic evidence;

- Established reimbursement coverage linked to our unique regulatory label;
- Procedure-focused approach to product innovation and service;
- Strong relationships and engagement with key medical societies and governmental agencies;
- Broad intellectual property portfolio; and
- Industry-experienced senior management team.

***Our Market Opportunity***

Carotid artery disease is one of the leading causes of stroke, and stroke is one of the most catastrophic, debilitating, and costly conditions worldwide. The consequences of stroke can include difficulty talking, memory loss, cognitive issues, paralysis or loss of muscle movement, inability to attend to bodily needs or care, pain, emotional problems, and death. In 2018, carotid artery disease was prevalent in approximately 4.3 million people in the United States, and an estimated 427,000 patients in the United States were diagnosed with carotid artery disease severe enough to warrant treatment in order to prevent a future stroke.

Once a patient is diagnosed with carotid artery disease, medical management is recommended, which includes lifestyle modifications and pharmaceutical treatments. Carotid revascularization treatment may be recommended in addition to medical management. The treatment paradigm is influenced by the patient's symptom status, disease progression and degree of stenosis, as well as factors that may place them at higher risk of adverse events.

***Existing Alternatives for Carotid Revascularization and Their Limitations***

Existing treatment options for carotid revascularization procedures include CEA and CAS. As shown in multiple randomized trials, both surgical removal of plaque with CEA and stenting of plaque with CAS have demonstrated clinical effectiveness in reducing long-term stroke risk. However, CEA and CAS have been associated with serious procedure-related adverse events that present within 30 days of treatment. We believe the procedural hazards of CEA and CAS limit their wider adoption in patients with carotid artery disease treated with medical management alone.

- ***Carotid Endarterectomy, or CEA:*** CEA is an invasive surgical procedure that involves a ten- to fifteen-centimeter incision in the neck to cut open the carotid arteries and remove the plaque. Data from large randomized clinical trials have demonstrated that CEA in addition to medical management is more effective at reducing long-term stroke risk than medical management alone, which has contributed to solidifying CEA as the standard of care. However, these trials and other studies have also indicated that CEA can result in known procedure-related adverse events, including cranial nerve injuries, heart attack and even stroke and death. Given the large incision, CEA also presents a risk of wound complications, including bleeding and infection. These adverse events can also lead to long hospital stays and lengthy recovery periods that are costly to providers and payers.
- ***Transfemoral Carotid Artery Stenting, or CAS:*** CAS uses minimally-invasive techniques to place a stent in the carotid artery. In a CAS procedure, a small puncture is made in the groin and a physician navigates catheters through the arteries of the body about three feet to the neck where a stent is placed. While CAS is less invasive than CEA, multiple randomized clinical studies and real-world registries have consistently shown an almost two-fold increase in the risk of stroke within 30 days following treatment, relative to CEA. As a result, CAS is performed in a minority of carotid revascularization procedures, consisting of only 14% of the estimated 168,000 carotid revascularization procedures in the United States in 2018.

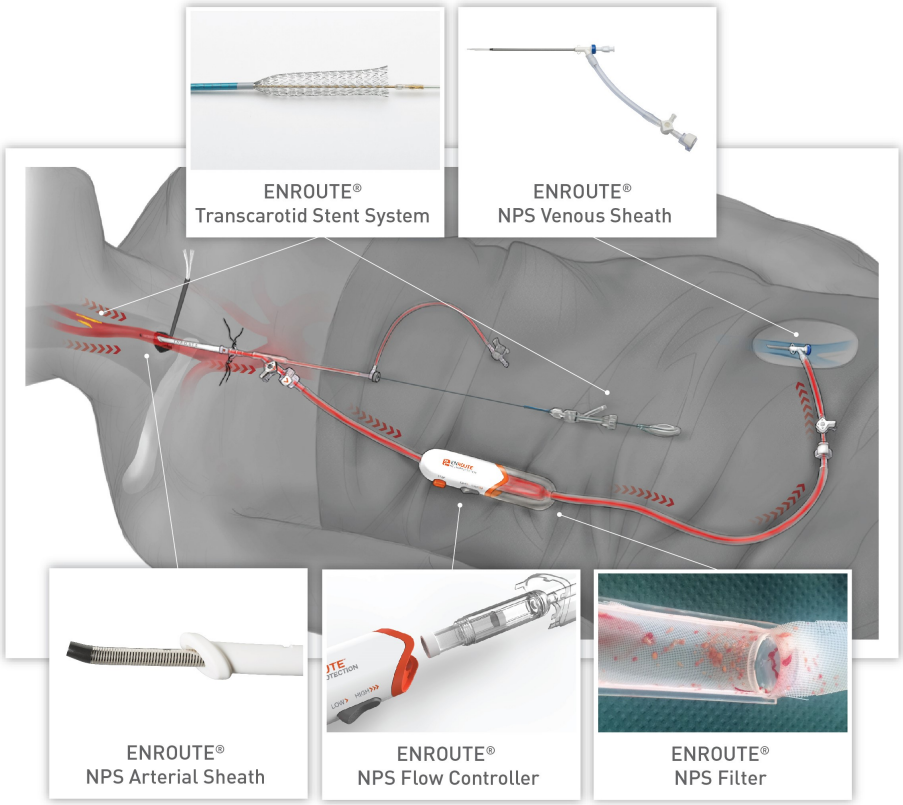
***Our Solution***

With our portfolio of TCAR products we have pioneered a new approach for the treatment of carotid artery disease and are seeking to establish TCAR as the standard of care.

TCAR relies on two novel concepts: minimally-invasive direct carotid access in the neck, and high-rate blood flow reversal during the procedure to protect the brain. The TCAR procedure begins with a two- to three-centimeter incision slightly above the collarbone, thereby obviating the need to maneuver catheters from the groin. A puncture is made into the carotid artery using our transcarotid access kit, after which the arterial sheath of our ENROUTE NPS is placed and then connected to the flow controller and then the venous sheath in the patient's groin, allowing for initiation of flow reversal. The pressure gradient between the high-pressure arterial system in the neck and the low-pressure venous system in the groin creates the blood flow reversal, which redirects dislodged plaque and debris away from the brain, where it is captured in an external filter in our system.

While the brain is protected by flow reversal, our guidewire is navigated across the lesion and our ENROUTE stent is delivered and placed in the carotid artery to stabilize the plaque against the wall of the artery, trapping the lesion and reducing the risk of a future stroke. After our ENROUTE stent is implanted, the blood flow is returned to normal, the ENROUTE NPS is removed, and the artery and small wound are sutured closed.

The following diagram depicts our portfolio of TCAR products:



We believe the results of our clinical studies provide compelling evidence that TCAR offers a reduction in 30-day and long-term stroke risk with a low rate of adverse events from the procedure. We believe the growing clinical evidence base from our ongoing and future studies and the TCAR Surveillance Project, an ongoing open-ended registry sponsored by the Society for Vascular Surgery, will continue to drive confidence in the procedure and support continued adoption.

We believe that TCAR offers other valuable benefits for providers and payers, including predictable and short procedure times, short hospital stays, and reduced in-hospital and 30-day adverse events. We believe these benefits can lead to more accountable care and improved provider economics and payer value.

***Our Target Market***

We are working to establish TCAR as the preferred alternative to both CEA and CAS for the treatment of patients with carotid artery disease. Because TCAR offers clinically proven, minimally-invasive reduction in stroke risk, we believe that TCAR offers a better solution for the approximately 168,000 patients treated in the United States in 2018, most of whom were treated with either CEA or CAS, which we estimate to be a near-term market conversion opportunity greater than $1.0 billion.

Currently, our ENROUTE stent is indicated for use in patients who are considered at high risk for adverse events from CEA, or high surgical risk. The labeled indications for use for our other products, including the ENROUTE NPS, are agnostic to surgical risk status. According to published studies and primary research, we believe the high surgical risk population represents approximately two-thirds, or over 111,000, of the approximately 168,000 patients treated in the United States in 2018, most of whom were treated for carotid artery disease with either CEA or CAS. We are currently focused on clinical development activities to support label expansion for our ENROUTE stent to patients who are at standard risk for adverse events from CEA, or standard surgical risk. We would then seek an associated expansion in CMS reimbursement coverage.

Additionally, we believe that as our technology becomes more widely adopted, TCAR may become a compelling alternative for patients who are treated with medical management alone each year. As a result, we believe the potential addressable opportunity for TCAR includes the estimated 427,000 individuals in the United States who were diagnosed with carotid artery disease, representing a total U.S. target market opportunity of approximately $2.6 billion in 2018.

While our current commercial focus is on the U.S. market, our ENROUTE stent and ENROUTE NPS have obtained CE Mark approval, allowing us to commercialize in Europe in the future. We also intend to pursue regulatory clearances in China, Japan, and other select international markets. Carotid artery disease and stroke are prevalent, devastating and costly conditions worldwide and we estimate that a significant opportunity exists for TCAR outside the United States, as the United States represents only 10% of the estimated global incidence of ischemic stroke.

## Our Growth Strategy

Our mission is to be the global leader in the treatment of carotid artery disease. We seek to establish TCAR as the standard of care for carotid revascularization by converting the base of existing CEA and CAS procedures and expanding the market to include patients treated with medical management alone. We also have a broad intellectual property platform and, in the future, we intend to leverage our expertise and the physiologic and engineering advantages made possible by our transcarotid approach to develop new products targeting procedures and vascular disease states in the heart, aortic arch and brain.

Our growth strategies include:

- Strategically expanding our U.S. sales force and marketing activities;

- Scaling professional education to drive physician use;
- Increasing TCAR adoption;
- Building our clinical evidence base;
- Broadening the indication for the ENROUTE stent and expanding reimbursement;
- Pursuing international markets; and
- Continuing our history of innovation in and beyond TCAR.

## Risks Associated with our Business

Our business is subject to numerous risks and uncertainties, including those highlighted in the section entitled "Risk Factors." These risks include, but are not limited to, the following:

- We are an early-stage company with a history of net losses, we expect to incur operating losses in the future and we may not be able to achieve or sustain profitability. We have a limited history operating as a commercial company.
- We rely on, and currently sell products to enable TCAR, a single and new procedure. We have limited commercial sales experience with our portfolio of TCAR products, which makes it difficult to evaluate our current business, predict our future prospects and forecast our financial performance and growth.
- Our business is dependent upon the broad adoption of TCAR by hospitals and physicians.
- Adoption of TCAR depends upon positive clinical data and medical society recommendations, and negative clinical data or medical society recommendations would adversely affect our business.
- Our failure to adequately train physicians may lead to negative patient outcomes, affect adoption of TCAR and adversely affect our business.
- We have limited long-term data regarding the safety and effectiveness of our products, including our ENROUTE stent and TCAR generally. Any long-term data that is generated by clinical trials or otherwise involving our products may not be positive or consistent with our short-term data, which would adversely affect our business.
- TCAR involves surgical risks and is contraindicated in certain patients, which may limit adoption.
- We rely on Cardinal Health to supply the ENROUTE stent, and if Cardinal Health fails to supply the ENROUTE stent in sufficient quantities or at all, it will have a material adverse effect on our business, financial condition and results of operations.
- Our success will depend on our ability to obtain, maintain and protect our intellectual property rights.
- Changes in the regulatory environment may constrain or require us to restructure our operations, which may harm our revenue and operating results.
- Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

- We have disclosed that there is substantial doubt about our ability to continue as a going concern.
- We have identified two material weaknesses in our internal control over financial reporting and may identify additional material weaknesses in the future.

## Emerging Growth Company Status

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, presenting only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure in this prospectus, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation, an exemption from the requirements to obtain a non-binding advisory vote on executive compensation or golden parachute arrangements, and extended transition periods for complying with new or revised accounting standards. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of the completion of this offering, (2) the last day of the fiscal year in which we have total annual revenue of more than $1.07 billion, (3) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. We have irrevocably elected not to avail ourselves of the exemption from new or revised accounting standards and, therefore, are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

## Company Information

We were incorporated in Delaware on March 21, 2007 as Silk Road Medical, Inc. Our principal executive offices are located at 1213 Innsbruck Drive, Sunnyvale, CA 94089, and our telephone number is (408) 720-9002. Our website address is www.silkroadmed.com. The information on, or that may be accessed through, our website is not incorporated by reference into this prospectus and should not be considered a part of this prospectus.

To the extent that we continue to qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, after we cease to qualify as an emerging growth company, we will continue to be permitted to make certain reduced disclosures in our periodic reports and other documents that we file with the SEC.

## Trademarks

“Silk Road Medical,” the “Silk Road Medical” logo, “Enroute” and the “Enroute” logo, and "Enhance" are trademarks or registered trademarks of our company. Our logo and our other tradenames, trademarks and service marks appearing in this prospectus are our property. Other tradenames, trademarks and service marks appearing in this prospectus are the property of their respective owners. Solely for convenience, our trademarks and tradenames referred to in this prospectus appear without the ™ or ® symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

# THE OFFERING

| | |
|---|---|
| **Common stock offered by us** | 6,000,000 shares |
| **Common stock outstanding after this offering** | 30,228,959 shares |
| **Underwriters' option to purchase additional shares** | The selling stockholders have granted the underwriters a 30-day option to purchase up to an additional 900,000 shares of Common Stock at the public offering price, less the underwriting discounts and commissions. |
| **Use of proceeds** | We estimate that the net proceeds to us from this offering will be approximately $109.1 million, at an initial public offering price of $20.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, net of actual payments of offering expenses of $233,000 as of December 31, 2018. We intend to use the net proceeds from this offering to expand our sales force and operations, increase our research and development activities, conduct or sponsor clinical studies and trials, expand internationally, and provide for working capital and other general corporate purposes. We may use a portion of the net proceeds to acquire complementary products, technologies, intellectual property or businesses; however, we currently do not have any agreements or commitments to complete any such transactions and are not involved in negotiations regarding such transactions. We will not receive any net proceeds from the sale of shares of common stock by the selling stockholders if the underwriters exercise their option to purchase additional shares. See "Use of Proceeds." |
| **Risk factors** | See "Risk Factors" beginning on page 13 and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock. |
| **Nasdaq Stock Market symbol** | SILK |

We refer to our Series A redeemable convertible preferred stock, Series A-1 redeemable convertible preferred stock, Series B redeemable convertible preferred stock and Series C redeemable convertible preferred stock as our convertible preferred stock in this prospectus, as well as for financial reporting purposes and in the financial tables included in this prospectus, as more fully explained in Note 8 to our audited consolidated financial statements. In this prospectus (as well as for financial reporting purposes and in the financial tables included in this prospectus as more fully described in Note 8 to our audited consolidated financial statements), we refer to our outstanding warrants as warrants to purchase shares of redeemable convertible preferred stock and common stock.

The number of shares of common stock that will be outstanding after this offering is based on 24,228,959 shares of common stock outstanding, assuming the conversion of all of our outstanding shares of convertible preferred stock and the automatic net exercise of outstanding warrants to purchase shares of convertible preferred stock and common stock as of December 31, 2018, in each case into common stock upon completion of this offering, at the initial public offering price of $20.00 per share, and excludes:

- 4,364,377 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock outstanding as of December 31, 2018, with a weighted-average exercise price of $3.79 per share;
- 32,950 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock granted after December 31, 2018, with a weighted-average exercise price of $11.29 per share; and
- 2,775,939 shares of common stock reserved for future grants under our stock-based compensation plans, consisting of:
    - 24,939 shares of common stock reserved for future grants under our 2007 Stock Plan, which shares will be added to the shares to be reserved under our 2019 Equity Incentive Plan;
    - 2,317,000 shares of common stock reserved for future grants under our 2019 Equity Incentive Plan, including 654,792 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock granted to certain of our executive officers, directors and new employees pursuant to our 2019 Equity Incentive Plan, with a grant date of April 3, 2019, and with an exercise price equal to $20.00 per share; and
    - 434,000 shares of common stock reserved for future issuance under our 2019 Employee Stock Purchase Plan.

In addition, unless otherwise indicated, all information in this prospectus assumes:

- a 1-for-2.7 reverse split of our capital stock that was effected prior to this offering;
- the conversion, in accordance with our existing amended and restated certificate of incorporation, of all shares of convertible preferred stock outstanding as of December 31, 2018 into an aggregate of 21,233,190 shares of common stock upon the completion of this offering;
- the automatic net exercise of outstanding warrants to purchase shares of convertible preferred stock into common stock as of December 31, 2018, upon the completion of this offering, at the initial public offering price of $20.00 per share, into an aggregate of 1,856,046 shares of common stock;
- the automatic net exercise of outstanding warrants to purchase shares of common stock as of December 31, 2018, upon the completion of this offering, at the initial public offering price of $20.00 per share, into an aggregate of 4,413 shares of common stock;
- no exercise by the underwriters of their option to purchase up to an additional 900,000 shares of common stock from the selling stockholders in this offering; and
- the adoption, filing and effectiveness of our amended and restated certificate of incorporation and amended and restated bylaws prior to the completion of this offering.

# SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth a summary of our historical consolidated financial data as of and for the periods indicated. We have derived the summary consolidated statements of operations data for the years ended December 31, 2017 and 2018 and the consolidated balance sheet data as of December 31, 2018 from our audited consolidated financial statements that are included elsewhere in this prospectus. You should read this data together with our consolidated financial statements and related notes thereto included elsewhere in this prospectus and the information under the captions "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The summary consolidated financial data included in this section are not intended to replace the audited consolidated financial statements and related notes thereto included elsewhere in this prospectus and are qualified in their entirety by the audited consolidated financial statements and related notes thereto included elsewhere in this prospectus. Our historical results are not necessarily indicative of our future results.

## Consolidated Statements of Operations Data:

| | Years Ended December 31, | |
|---|---|---|
| *(in thousands, except share and per share data)* | **2017** | **2018** |
| Revenue | $ 14,258 | $ 34,557 |
| Cost of goods sold | 5,129 | 10,874 |
| Gross profit | 9,129 | 23,683 |
| Operating expenses: | | |
| Research and development | 7,242 | 10,258 |
| Selling, general and administrative | 20,261 | 34,820 |
| Total operating expenses | 27,503 | 45,078 |
| Loss from operations | (18,374) | (21,395) |
| Interest income (expense), net | (3,909) | (4,172) |
| Other income (expense), net | 2,927 | (12,063) |
| Net loss | (19,356) | (37,630) |
| Net loss attributable to non-controlling interest | — | 1 |
| Net loss attributable to Silk Road Medical, Inc. common stockholders | $ (19,356) | $ (37,629) |
| Net loss per share attributable to Silk Road Medical, Inc. common stockholders, basic and diluted[(1)] | $ (44.58) | $ (39.16) |
| Weighted average common shares used to compute net loss per share attributable to Silk Road Medical, Inc. common stockholders, basic and diluted[(1)] | 434,158 | 960,882 |
| Pro forma net loss per share attributable to Silk Road Medical, Inc. common stockholders, basic and diluted [(1)] | | $ (1.07) |
| Pro forma weighted average common shares used to compute net loss per share attributable to Silk Road Medical, Inc. common stockholders, basic and diluted [(1)] | | 24,050,299 |

(1) See Note 2 to our consolidated financial statements for further details on the calculation of our historical and pro forma net loss per share, basic and diluted, and the weighted-average number of shares used in the per share amounts.

## Consolidated Balance Sheet Data:

| | As of December 31, 2018 | | |
|---|---|---|---|
| *(in thousands)* | **Actual** | **Pro Forma[1]** | **Pro Forma As Adjusted[2]** |
| Cash and cash equivalents | $ 24,990 | $ 24,990 | $ 134,073 |
| Working capital[3] | 27,824 | 27,824 | 137,624 |
| Total assets[4] | 40,881 | 40,881 | 149,013 |
| Long-term debt | 44,201 | 44,201 | 44,201 |
| Convertible preferred stock warrant liability | 16,091 | — | — |
| Convertible preferred stock | 105,235 | — | — |
| Accumulated deficit | (139,111) | (139,111) | (139,111) |
| Total stockholders' equity (deficit) | (134,553) | (13,227) | 95,623 |

(1) Reflects (i) the conversion of all of our outstanding shares of convertible preferred stock into an aggregate of 21,233,190 shares of our common stock, (ii) the automatic net exercise of outstanding warrants to purchase shares of convertible preferred stock and common stock into shares of common stock upon completion of this offering, at the initial public offering price of $20.00 per share, and the reclassification of our convertible preferred stock warrant liability to stockholders' equity (deficit), and (iii) the filing and effectiveness of our amended and restated certificate of incorporation, in each case, immediately upon completion of this offering.

(2) Reflects the pro forma adjustments described in footnote 1 above and the sale and issuance of 6,000,000 shares of common stock by us in this offering, based upon the initial public offering price of $20.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, net of actual payments of offering expenses of $233,000 as of December 31, 2018.

(3) We define working capital as current assets less current liabilities. Pro forma as adjusted working capital reflects the pro forma adjustments described in footnote 2 above and an adjustment to reflect the payment of accrued offering expenses of $717,000 as of December 31, 2018.

(4) Pro forma as adjusted total assets reflects the pro forma adjustments described in footnote 2 above and the adjustment to reclass offering expenses of $950,000 included in other assets as of December 31, 2018 against the net proceeds.

# RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this prospectus, including the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes thereto included elsewhere in this prospectus, before deciding whether to invest in shares of our common stock. The risks described below are not the only ones facing us. The occurrence of any of the following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition, results of operations and future prospects. In that event, the market price of our common stock could decline, and you could lose all or part of your investment. Please also see "Cautionary Notes Regarding Forward-Looking Statements" and "Market, Industry and Other Data."*

## Risks Related to Our Business

***We are an early-stage company with a history of net losses, we expect to incur operating losses in the future and we may not be able to achieve or sustain profitability. We have a limited history operating as a commercial company.***

We have incurred net losses since our inception in March 2007. For the years ended December 31, 2017 and 2018, we had a net loss of $19.4 million, and $37.6 million, respectively, and we expect to continue to incur additional losses in the future. As of December 31, 2018, we had an accumulated deficit of $139.1 million. To date, we have financed our operations primarily through equity and debt financings and from sales of our portfolio of TCAR products that enable transcarotid artery revascularization, or TCAR. The losses and accumulated deficit have primarily been due to the substantial investments we have made to develop our products, as well as for costs related to general research and development, including clinical and regulatory initiatives to obtain marketing approval, sales and marketing efforts and infrastructure improvements.

We fully commercialized our products in the United States in 2016 and therefore do not have a long history operating as a commercial company. Over the next several years, we expect to continue to devote a substantial amount of our resources to expand commercialization efforts and increase adoption of TCAR using our products, improve reimbursement for TCAR, and develop additional products. In addition, as a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. Accordingly, we expect to continue to incur operating losses for the foreseeable future and we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability in the future will make it more difficult to finance our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition and results of operations and cause the market price of our common stock to decline. In addition, failure of our products to significantly penetrate the target markets would negatively affect our business, financial condition and results of operations.

***We rely on, and currently sell products to enable, TCAR, a single and new procedure. We have limited commercial sales experience regarding TCAR, which makes it difficult to evaluate our current business, predict our future prospects and forecast our financial performance and growth.***

To date, all of our revenue has been derived, and we expect it to continue to be derived in the near term, from sales of our products that enable TCAR. TCAR is a new treatment option for certain patients diagnosed with carotid artery disease and, as a result, physician awareness of TCAR and our products, and experience with TCAR and our products, is limited. As a result, our products have limited product and brand recognition and TCAR has limited recognition within the medical industry. The novelty of TCAR and our products that enable the procedure, together with our limited commercialization

experience, make it difficult to evaluate our current business and predict our future prospects. A number of factors that are outside of our control may contribute to fluctuations in our financial results, including:

- Physician and hospital demand for our products and adoption of TCAR, including the rate at which physicians recommend our products and TCAR to their patients;
- Positive or negative media coverage, or public, patient and/or physician perception, of our products and TCAR or competing products and procedures;
- Any safety or effectiveness concerns that arise regarding our products or TCAR;
- Unanticipated delays in product development or product launches;
- Our ability to maintain our current or obtain further regulatory clearances or approvals;
- Delays in, or failure of, product and component deliveries by our third-party suppliers; and
- Introduction of new products or procedures for treating carotid artery disease that compete with our products.

It is therefore difficult to predict our future financial performance and growth, and such forecasts are inherently limited and subject to a number of uncertainties. If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer.

In addition, because we devote substantially all of our resources to our products that enable TCAR and rely on our products and the adoption of TCAR as our sole source of revenue, any factors that negatively impact our products or TCAR, or result in a decrease in sales of products, could have a material adverse effect on our business, financial condition and results of operations.

***Our business is dependent upon the broad adoption of TCAR by hospitals and physicians.***

To date, a substantial majority of our product sales and revenue have been derived from a limited number of hospitals and physicians who have adopted TCAR. Our future growth and profitability largely depend on our ability to increase physician awareness of TCAR and on the willingness of physicians to adopt our products and TCAR, and to recommend the procedure to their patients. Physicians may not adopt our products unless they are able to determine, based on experience, clinical data, medical society recommendations and other analyses, that our products provide a safe and effective treatment alternative for carotid artery disease. Even if we are able to raise awareness among physicians, physicians tend to be slow in changing their medical treatment practices and may be hesitant to select our products or TCAR for recommendation to patients for a variety of reasons, including:

- Long-standing relationships with competing companies and distributors that sell other products, such as stents and embolic protection devices for transfemoral carotid artery stenting, or CAS;
- Competitive response and negative selling efforts from providers of alternative carotid revascularization products;
- Lack of experience with our products and concerns that we are relatively new to market;
- Perceived liability risk generally associated with the use of new products and procedures;
- Lack or perceived lack of sufficient clinical evidence, including long-term data, supporting clinical benefits;
- Reluctance to change to or use new products and procedures;

- Perceptions that our products are unproven; and
- Time commitment and skill development that may be required to gain familiarity and proficiency with TCAR and our products.

Physicians play a significant role in determining the course of a patient's treatment for carotid artery disease and, as a result, the type of treatment that will be recommended or provided to a patient. We focus our sales, marketing and education efforts primarily on vascular surgeons, and aim to educate referring physicians such as vascular surgeons, cardiologists, radiologists, neurologists, neurosurgeons and general practitioners regarding the patient population that would benefit from TCAR. However, we cannot assure you that we will achieve broad education or market acceptance among these practitioners. For example, if diagnosing physicians that serve as the primary point of contact for patients are not made aware of TCAR, they may not refer patients to physicians for treatment using our products, and those patients may instead not seek treatment at all or may be treated with alternative procedures. In addition, some physicians may choose to utilize TCAR on only a subset of their total patient population or may not adopt TCAR at all. Further, as TCAR is a new procedure, it may not fit into the workstreams of certain physicians. If we are not able to effectively demonstrate that TCAR is beneficial in a broad range of patients, adoption of TCAR will be limited and may not occur as rapidly as we anticipate or at all, which would have a material adverse effect on our business, financial condition and results of operations. We cannot assure you that TCAR or our products will achieve broad market acceptance among hospitals and physicians. Any failure of TCAR or our products to satisfy demand or to achieve meaningful market acceptance and penetration will harm our future prospects and have a material adverse effect on our business, financial condition and results of operations.

In addition, the medical device industry's relationship with physicians is under increasing scrutiny by the Health and Human Services Office of the Inspector General, or OIG, the Department of Justice, or DOJ, state attorneys general, and other foreign and domestic government agencies. Our failure to comply with laws, rules and regulations governing our relationships with physicians, or an investigation into our compliance by the OIG, DOJ, state attorneys general or other government agencies, could significantly harm our business.

In most cases, before physicians can use our products for the first time, our products must be approved for use by a hospital's new product or value analysis committee, or the staff of a hospital or health system. Following such approval, we may be required to enter into a purchase contract. Such approvals or requirements to enter into a purchase contract could deter or delay the use of our products by physicians. We cannot provide assurance that our efforts to obtain such approvals, enter into purchase contracts, or generate adoption will be successful or increase the use of our products, and if we are not successful, it could have a material adverse effect on our business, financial condition and results of operations.

***Adoption of TCAR depends upon positive clinical data and medical society recommendations, and negative clinical data or medical society recommendations would adversely affect our business.***

The rate of adoption of TCAR and sales of our products that facilitate the procedure is heavily influenced by clinical data. Although the Society for Vascular Surgery's TCAR Surveillance Project contains real world data comparing procedures, we have not conducted head-to-head clinical trials to compare TCAR to the procedures historically available to patients, such as carotid endarterectomy, or CEA, or CAS, which may limit the adoption of TCAR. Additionally, the Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis clinical trial is currently being conducted by the National Institutes of Health, which compares the effectiveness of each of CEA and CAS with best medical management solutions. Although enrollment is not expected to be completed until at least 2020, interim results could be released at any time. At the completion of the four-year follow-up, the trial could conclude that medical management alone achieves the same therapeutic results as surgical intervention,

which would have an adverse impact on the adoption of TCAR. Finally, our competitors and third parties may also conduct clinical trials of our products without our participation. Unfavorable or inconsistent clinical data from existing or future clinical trials conducted by us, our competitors or third parties, the interpretation of our clinical data or findings of new or more frequent adverse events, could have a material adverse effect on our business, financial condition and results of operations.

As physicians are influenced by guidelines issued by physician organizations, such as the Society for Vascular Surgery, the rate of adoption of TCAR and sales of our products that facilitate the procedure is also heavily influenced by medical society recommendations. We believe the Society for Vascular Surgery's Clinical Practice Guidelines, or SVS Guidelines, are of particular importance to the broader market acceptance of TCAR. The most current SVS Guidelines on the management of carotid artery disease, published in 2011, do not specifically mention TCAR as a treatment for carotid artery disease, but generally discuss CAS and embolic protection methods, including flow reversal. If the next version of the SVS Guidelines do not recommend TCAR, or if the Society for Vascular Surgery issues a negative statement regarding TCAR, physicians may not adopt or continue to use TCAR or our products, which would have a material adverse effect on our business, financial condition and results of operations. Additionally, if key opinion leaders who currently support TCAR cease to recommend TCAR or our products, our business, financial condition and results of operations will be adversely affected.

***Adoption of TCAR depends upon appropriate physician training, and inadequate training may lead to negative patient outcomes, affect adoption of TCAR and adversely affect our business.***

The success of TCAR depends in part on the skill of the physician performing the procedure and on our customers' adherence to appropriate patient selection and proper techniques provided in training sessions conducted by our training faculty. For example, we train our customers to ensure correct use of our ENROUTE NPS and proper deployment of our ENROUTE stent. However, physicians rely on their previous medical training and experience when performing TCAR, and we cannot guarantee that all such physicians will have the necessary surgical skills to perform the procedure. We do not control which physicians perform TCAR or how much training they receive, and physicians who have not completed our training sessions may nonetheless attempt to perform TCAR. If physicians perform TCAR in a manner that is inconsistent with its labeled indications, with components that are not our products or without adhering to or completing our training sessions, their patient outcomes may not be consistent with the outcomes achieved in our clinical trials. This result may negatively impact the perception of patient benefit and safety and limit adoption of TCAR and our products that facilitate the procedure, which would have a material adverse effect on our business, financial condition and results of operations.

***We have limited long-term data regarding the safety and effectiveness of our products, including our ENROUTE stent and TCAR generally.***

Our products enable TCAR, which is a novel procedure, and our success depends on acceptance of our products and TCAR by the medical industry, including physicians and hospitals. The FDA reviews our products, and the stent manufactured for us by Cordis, for safety and effectiveness, prior to commercial launch of these products. Thereafter, physicians, through their own use of the products and evaluation of clinical data, make their own decisions as to whether our products are safe and effective for their patients and improve their clinical outcomes. Important factors upon which the effectiveness of our products, including our ENROUTE stent, will be measured are long-term data regarding the risk of stroke and death and the rate of restenosis following TCAR. The long-term clinical benefits of procedures that use our products are not known. There is limited data on the long-term performance of carotid stents beyond three years after implantation. We have limited data on the ENROUTE stent up to one year. Any failure of our stent or in-stent restenosis of the carotid artery following deployment of the stent could deter physicians from adopting our products and could have a material adverse effect on our business, financial condition and results of operations.

The results of short-term clinical experience of our products do not necessarily predict long-term clinical benefit. We believe that physicians will compare the rates of long-term risk of stroke and death, as well as restenosis and reintervention for procedures using our products, against alternative procedures, such as CEA and CAS. If the long-term data do not meet physicians' expectations, or if long-term data indicate that our products are not as safe or effective as other treatment options or as current short-term data would suggest, our products may not become widely adopted, physicians may recommend alternative treatments for their patients and our business our be harmed.

***If we are not able to maintain adequate levels of third-party coverage and reimbursement for the procedures using our products, if third parties rescind or modify their coverage or delay payments, or if patients are left with significant out-of-pocket costs, it would have a material adverse effect on our business, financial condition and results of operations.***

TCAR is currently covered under certain circumstances for certain patients by the Centers for Medicare and Medicaid Services, and has been covered by some commercial payers, independent networks and other entities not governed by the National Coverage Determination. In the United States, we derive our revenue from sales to hospital and medical centers, which typically bill all or a portion of the costs and fees associated with our products to various third-party payers, including Medicare, Medicaid, private commercial insurance companies, health maintenance organizations and other healthcare-related organizations, and then bill patients for any applicable deductibles or co-payments. For example, our contracts are with the hospitals and medical centers that purchase our products for use with TCAR and not with the commercial payers. As a result, access to adequate coverage and reimbursement for our products by third-party payers is essential to the acceptance of our products by our customers.

However, in the United States, there is no uniform policy of coverage and reimbursement for medical device products and services among third-party payers, so coverage and reimbursement can differ significantly from payer to payer, and each coverage decision and level of reimbursement is independent. As a result, third-party reimbursement may not be available or adequate for our products, and there is no guarantee that we will be able to maintain our current levels of coverage or reimbursement or be able to expand coverage to other insurance carriers. Further, payers continually review new technologies for possible coverage and can, without notice, deny coverage for products and procedures or delay coverage approval until further clinical data is available. As a result, the coverage determination process is often a time-consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be obtained, or maintained if obtained. If third-party reimbursement is not available or adequate for our products, or if there is any decline in the amount that payers are willing to reimburse our customers for our products, new customers may not adopt, or may reduce their rate of adoption of, our products and we could experience additional pricing pressure for us, any of which could have a material adverse effect on our business, financial condition and results of operations.

Our products are reimbursed primarily on a per-patient prior authorization basis for patients covered by commercial insurers and on a medical necessity basis for most patients covered by Medicare. Based on reimbursement information regarding CEA and CAS, we estimate that approximately 75% of TCAR procedures are reimbursed by Medicare/Medicaid and approximately 25% are reimbursed by commercial payers. Current Procedure Terminology, or CPT, codes are developed and issued by the American Medical Association, or AMA. The U.S. Centers for Medicare & Medicaid Services, or CMS, determines Medicare payment based on formulas within the Medicare Resource-Based Relative Value Scale, which uses Relative Value Units, or RVUs. The RVU totals for a CPT code are determined and periodically updated by an AMA/Specialty Society RVS Update Committee, or RUC. In the future, reimbursement for our products may change based on a new RUC review. If the Society for Vascular Surgery recommended changes to the RVUs or declined to support the use of TCAR or the Medicare National Coverage Determination no longer covers TCAR, there would be a material adverse effect on our business, financial condition and results of operations. If this were to occur, commercial insurance companies could also adjust payment rates at which they reimburse our products. Other carotid artery disease treatments, such

as CEA, may be more widely covered or subject to different co-pay policies and requirements. If patients are required to cover all or a part of the cost of our products out-of-pocket, they may be less likely to elect to use our products and/or undergo the procedure. Additionally, patients may elect to reduce or defer out-of-pocket costs during times of economic uncertainty or periods of legislative change. If hospital, physician and/or patient demand for TCAR, and thus our products that facilitate the procedure, is adversely affected by third-party reimbursement policies and decisions, it will have a material adverse effect on our business, financial condition and results of operations.

Internationally, reimbursement systems in foreign markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In certain international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Additionally, many international markets have government-managed healthcare systems that control reimbursement for products and procedures. In most markets there are both private insurance systems and government-managed systems. If sufficient levels of coverage and reimbursement are not available for our current or future products, in either the United States or internationally, the demand for our products and our revenues will be adversely affected.

Additionally, when payers combine their operations, the combined company may elect to reimburse for TCAR at the lowest rate paid by any of the participants in the consolidation or use its increased size to negotiate reduced rates. If one of the payers participating in the consolidation does not reimburse for TCAR at all, the combined company may elect not to reimburse for TCAR, which would adversely impact our business, financial condition and results of operations.

***If we fail to comply with our obligations in our intellectual property license from Cardinal Health, we could lose license rights that are important to our business.***

We are a party to a license agreement with Cordis Corporation, or Cordis, which was acquired by Cardinal Health, under which Cordis has granted us a worldwide, non-exclusive, royalty-bearing license to certain of its intellectual property related to the PRECISE® carotid stent for transcervical treatment of carotid artery disease with an intravascular stent for certain applications for accessing blood vessels through the neck and cervical area. This license agreement imposes, and we expect that any future license agreements will impose, certain diligence, royalty, and other obligations on us. If we fail to comply with these obligations, our licensors, including Cardinal Health, may have the right to reduce the scope of our rights or terminate these agreements, in which event we may not be able to develop and market any product that is covered by these agreements. Termination of this license for failure to comply with such obligations or for other reasons, or reduction or elimination of our licensed rights under it or any other license, may result in our having to negotiate new or reinstated licenses on less favorable terms or our not having sufficient intellectual property rights to operate our business or cause us to enter into a new license for a different stent. The occurrence of such events could materially harm our business and financial condition.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we in-license, and any failure by us or our licensors, including Cordis, to obtain, maintain, defend and enforce these rights could have a material adverse effect on our business. In some cases we do not have control over the prosecution, maintenance or enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

***We rely on Cardinal Health to supply the ENROUTE stent, and if Cardinal Health fails to supply the ENROUTE stent in sufficient quantities or at all, it will have a material adverse effect on our business, financial condition and results of operations.***

We rely on Cardinal Health to manufacture the ENROUTE stent pursuant to a supply agreement between us and Cordis Corporation, which was acquired by Cardinal Health. We strive to maintain an inventory of several months' worth of ENROUTE stents to guard against potential shortfalls in supply, and we estimate that it would take one to two years to find an alternative supplier for our ENROUTE stent and multiple years to identify and seek approval for another stent, and in each case qualify it for use with our other products. In addition, Cardinal Health currently manufactures the ENROUTE stent at a facility in Juarez, Mexico. The current political and trade relationship between the United States and Mexico is strained and may deteriorate. If Cardinal Health's ability to manufacture the ENROUTE stent is interrupted as a result, or if Cardinal Health breaches its supply agreement with us, we may not have a sufficient number of stents for delivery to support TCAR procedures. Any shortfall in the supply of ENROUTE stents may result in lower adoption rates for TCAR, fewer TCAR procedures being performed generally, and a material adverse effect on our business, financial condition and results of operations.

***TCAR involves surgical risks and is contraindicated in certain patients, which may limit adoption.***

Risks of TCAR using our products include the risks that are common to endovascular procedures, including perforation, dissection, embolization, bleeding, infection, nerve injury and restenosis. Endovascular procedures occurring in the common carotid artery also include the additional risks of stroke, heart attack and death. We are aware of certain characteristics and features of TCAR that may prevent widespread market adoption, including the fact that physicians would need to adopt a new procedure, and that training for physicians will be required to enable them to effectively operate our products.

Our current products are contraindicated, and therefore should not be used, in certain patients. Our ENROUTE NPS is contraindicated in patients in whom antiplatelet and/or anticoagulation therapy is contraindicated; patients with uncorrected bleeding disorders; patients with severe disease of the ipsilateral common carotid artery; and patients with uncontrollable intolerance to flow reversal. Our ENROUTE stent is contraindicated in patients in whom antiplatelet and/or anticoagulation therapy is contraindicated; patients in whom the ENROUTE NPS is unable to be placed; patients with uncorrected bleeding disorders; patients with known allergies to nitinol; and patients with lesions in the ostium of the common carotid artery. Our ENHANCE peripheral access kit is contraindicated in patients with a known or suspected obstruction in the vessel. Our ENROUTE guidewire is contraindicated in patients judged not acceptable for percutaneous intervention. Additionally, patients with less than five centimeters of common carotid artery free of significant disease are not eligible for TCAR.

***We have limited experience manufacturing our products in commercial quantities and we face manufacturing risks that may adversely affect our ability to manufacture products and could reduce our gross margins and negatively affect our business and operating results.***

Our business strategy depends on our ability to manufacture our current and future products in sufficient quantities and on a timely basis to meet customer demand, while adhering to product quality standards, complying with regulatory quality system requirements and managing manufacturing costs. We have a facility located in Sunnyvale, California, where we assemble, inspect, package, release and ship our products. We currently produce our ENROUTE NPS at this facility, and we do not have redundant facilities. If this facility suffers damage, or a force majeure event, this could materially impact our ability to operate.

We are also subject to numerous other risks relating to our manufacturing capabilities, including:

- Quality and reliability of components, sub-assemblies and materials that we source from third-party suppliers, who are required to meet our quality specifications, all of whom are our single source suppliers for the products they supply;
- Our inability to secure components, sub-assemblies and materials in a timely manner, in sufficient quantities or on commercially reasonable terms;
- Our inability to maintain compliance with quality system requirements or pass regulatory quality inspections;
- Our failure to increase production capacity or volumes to meet demand;
- Our inability to design or modify production processes to enable us to produce future products efficiently or implement changes in current products in response to design or regulatory requirements; and
- Difficulty identifying and qualifying, and obtaining new regulatory approvals, for alternative suppliers for components in a timely manner.

These risks are likely to be exacerbated by our limited experience with our current products and manufacturing processes. As demand for our products increases, we will have to invest additional resources to purchase components, sub-assemblies and materials, hire and train employees and enhance our manufacturing processes. If we fail to increase our production capacity efficiently, we may not be able to fill customer orders on a timely basis, our sales may not increase in line with our expectations and our operating margins could fluctuate or decline. In addition, although we expect some of our products in development to share product features, components, sub-assemblies and materials with our existing products, the manufacture of these products may require modification of our current production processes or unique production processes, the hiring of specialized employees, the identification of new suppliers for specific components, sub-assemblies and materials or the development of new manufacturing technologies. It may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable or to maintain current operating margins, all of which could have a material adverse effect on our business, financial condition and results of operations.

***We depend on a limited number of single source suppliers to manufacture our components, sub-assemblies and materials, which makes us vulnerable to supply shortages and price fluctuations that could have a material adverse effect on our business, financial condition and results of operations.***

We rely on single source suppliers for the components, sub-assemblies and materials for our products. These components, sub-assemblies and materials are critical and there are relatively few alternative sources of supply. We have not qualified or obtained necessary regulatory approvals for additional suppliers for most of these components, sub-assemblies and materials, and we do not carry a significant inventory of these items. While we believe that alternative sources of supply may be available, we cannot be certain whether they will be available if and when we need them, or that any alternative suppliers would be able to provide the quantity and quality of components and materials that we would need to manufacture our products if our existing suppliers were unable to satisfy our supply requirements. To utilize other supply sources, we would need to identify and qualify new suppliers to our quality standards and obtain any additional regulatory approvals required to change suppliers, which could result in manufacturing delays and increase our expenses.

Our dependence on third-party suppliers subjects us to a number of risks that could impact our ability to manufacture our products and harm our business, including:

- Interruption of supply resulting from modifications to, or discontinuation of, a supplier's operations;
- Delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's failure to produce components that consistently meet our quality specifications;
- Price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;
- Inability to obtain adequate supply in a timely manner or on commercially reasonable terms;
- Difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- Inability of suppliers to comply with applicable provisions of the QSR or other applicable laws or regulations enforced by the FDA and state regulatory authorities;
- Inability to ensure the quality of products manufactured by third parties;
- Production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications; and
- Delays in delivery by our suppliers due to changes in demand from us or their other customers.

Although we require our third-party suppliers to supply us with components that meet our specifications and comply with applicable provisions of the QSR and other applicable legal and regulatory requirements in our agreements and contracts, and we perform incoming inspection, testing or other acceptance activities to ensure the components meet our requirements, there is a risk that our suppliers will not always act consistent with our best interests, and may not always supply components that meet our requirements or supply components in a timely manner.

***Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.***

We seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions, but keep limited components, sub-assemblies, materials and finished products on hand. To ensure adequate inventory supply and manage our operations with our third-party manufacturers and suppliers, we forecast anticipated materials requirements and demand for our products in order to predict inventory needs and then place orders with our suppliers based on these predictions. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including our limited historical commercial experience regarding TCAR, rapid growth, failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our products, our failure to accurately forecast customer acceptance of new products, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions.

Inventory levels in excess of customer demand may result in a portion of our inventory becoming obsolete or expiring, as well as inventory write-downs or write-offs, which would impair the strength of our brand. Conversely, if we underestimate customer demand for our products or our own requirements for components, subassemblies and materials, our third-party manufacturers and suppliers may not be able to deliver components, sub-assemblies and materials to meet our requirements, which could result in inadequate inventory levels or interruptions, delays or cancellations of deliveries to our customers, any of which would damage our reputation, customer relationships and business. In addition, several components, sub-assemblies and materials incorporated into our products require lengthy order lead

times, and additional supplies or materials may not be available when required on terms that are acceptable to us, or at all, and our third-party manufacturers and suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, any of which could have an adverse effect on our ability to meet customer demand for our products and our results of operations.

***Our quarterly and annual results may fluctuate significantly and may not fully reflect the underlying performance of our business.***

Our quarterly and annual results of operations, including our revenue, profitability and cash flow, may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Fluctuations in quarterly and annual results may decrease the value of our common stock. Because our quarterly results may fluctuate, period-to-period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing.

***We have a limited total addressable market based on our current labeling restrictions.***

The total addressable market for TCAR is limited by a number of factors. Approximately 168,000 patients with carotid artery disease in the United States received treatment in the form of surgical or endovascular intervention in 2018. Of this group, we estimate that approximately one-third would be outside the scope of the FDA-approved labeling for the ENROUTE stent, as those patients are not deemed to be at high risk for adverse events from CEA, or high surgical risk. The current FDA-approved labeling for the ENROUTE stent is limited to high risk patients. Patients at high risk for adverse events from CEA are defined as having significant comorbidities or anatomic risk factors, or advanced age, that would make them poor candidates for CEA. Furthermore, the safety and effectiveness of TCAR has not been established for certain patients. For example, the FDA-cleared labeling for the ENROUTE NPS states that patients should have at least five centimeters of common carotid artery free of significant disease for initial access to the artery and positioning of the ENROUTE sheath. In addition, per the FDA-approved labeling for the ENROUTE stent, TCAR is limited to asymptomatic patients with carotid artery stenosis of at least 80% and symptomatic patients with carotid artery stenosis of at least 50%, both of which must also be high surgical risk. In addition, physicians may choose to perform CEA in patients with certain anatomical characteristics, including heavily calcified carotid arteries, calcified lesions and severe vessel tortuousity. Finally, current labeling for our products includes contraindications for certain patients, thus further reducing our total addressable market.

***Full penetration of the addressable market for TCAR is dependent upon labeling and reimbursement expansion initiatives.***

The ENROUTE stent is not currently indicated for use in standard surgical risk patients. To access a larger portion of the market for carotid artery disease, we will need to obtain approval by the FDA for a label expansion of the ENROUTE stent in standard surgical risk patients and obtain corresponding reimbursement coverage expansion for TCAR. FDA approval of an ENROUTE stent label expansion will require additional data from clinical studies, which we intend to pursue. However, there are no guarantees that we will be able to obtain such clinical data or FDA approval of a label expansion for the ENROUTE stent, or that any label expansion or additional reimbursement coverage will be sufficient to access a significantly larger portion of the market for carotid artery disease patients. If we are unable to obtain labeling and reimbursement coverage expansion, it may have a material adverse effect on our business, financial condition and results of operations.

***Changes in public health insurance coverage and government reimbursement rates for our products could affect the adoption of our products and our future revenue.***

The federal government is considering ways to change, and has changed, the manner in which healthcare services are paid for in the United States. Individual states may also enact legislation that impacts Medicaid payments to hospitals and physicians. In addition, CMS establishes Medicare payment levels for hospitals and physicians on an annual basis, which can increase or decrease payment to such entities. Internationally, medical reimbursement systems vary significantly from country to country, with some countries limiting medical centers' spending through fixed budgets, regardless of levels of patient treatment, and other countries requiring application for, and approval of, government or third-party reimbursement. Even if we succeed in bringing our products to market in additional foreign countries, uncertainties regarding future healthcare policy, legislation and regulation, as well as private market practices, could affect our ability to sell our products in commercially acceptable quantities at acceptable prices.

***Cost-containment efforts of our customers, purchasing groups and governmental organizations could have a material adverse effect on our sales and profitability.***

In an effort to reduce costs, many hospitals in the United States have become members of Group Purchasing Organizations, or GPOs, and Integrated Delivery Networks, or IDNs. GPOs and IDNs negotiate pricing arrangements with medical device companies and distributors and then offer these negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. Bids are generally solicited from multiple providers with the intention of driving down pricing or reducing the number of vendors. Due to the highly competitive nature of the GPO and IDN contracting processes, we may not be able to obtain new, or maintain existing, contract positions with major GPOs and IDNs. Furthermore, the increasing leverage of organized buying groups may reduce market prices for our products, thereby reducing our revenue and margins.

While having a contract with a GPO or IDN for a given product category can facilitate sales to members of that GPO or IDN, such contract positions can offer no assurance that any level of sales will be achieved, as sales are typically made pursuant to individual purchase orders. Even when a provider is the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN are generally free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause by the GPO or IDN upon 60 to 90 days' notice. Accordingly, the members of such groups may choose to purchase alternative products due to the price or quality offered by other companies, which could result in a decline in our revenue.

***We may not be able to achieve or maintain satisfactory pricing and margins for our products.***

Manufacturers of medical devices have a history of price competition, and we can give no assurance that we will be able to achieve satisfactory prices for our products or maintain prices at the levels we have historically achieved. Any decline in the amount that payers reimburse our customers for TCAR could make it difficult for customers to continue using, or to adopt, our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, our gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode. We will continue to be subject to significant pricing pressure, which could harm our business and results of operations.

***If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be harmed.***

Any growth that we experience in the future will require us to expand our sales personnel and manufacturing operations and general and administrative infrastructure. In addition to the need to scale

our organization, future growth will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. Rapid expansion in personnel could mean that less experienced people manufacture, market and sell our products, which could result in inefficiencies and unanticipated costs, reduced quality and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure. Our ability to manage our business and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

As demand for our products or any of our future products increases, we will need to continue to scale our capacity, expand customer service, billing and systems processes and enhance our internal quality assurance program. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available to facilitate the growth of our business. Failure to implement necessary procedures, transition to new processes or hire the necessary personnel could result in higher costs of processing data or inability to meet increased demand. If we encounter difficulty meeting market demand, quality standards or physician expectations, our reputation could be harmed and our business could suffer.

***If our manufacturing facility becomes damaged or inoperable, or if we are required to vacate a facility, we may be unable to produce the products we manufacture or we may experience delays in production or an increase in costs, which could adversely affect our results of operations.***

We currently maintain our research and development, manufacturing and administrative operations in a building located in Sunnyvale, California, which is situated on or near earthquake fault lines, and we do not have redundant facilities. Should our building be significantly damaged or destroyed by natural or man-made disasters, such as earthquakes, fires or other events, it could take months to relocate or rebuild, during which time our employees may seek other positions, our research, development and manufacturing would cease or be delayed and our products may be unavailable. Moreover, the use of a new facility or new manufacturing, quality control, or environmental control equipment or systems generally requires FDA review and approval of a PMA supplement. Because of the time required to authorize manufacturing in a new facility under FDA, the State of California and non-U.S. regulatory requirements, we may not be able to resume production on a timely basis even if we are able to replace production capacity in the event we lose manufacturing capacity. While we maintain property and business interruption insurance, such insurance has limits and would only cover the cost of rebuilding and relocating and lost revenue, but not general damage or losses caused by earthquakes or losses we may suffer due to our products being replaced by competitors' products. The inability to perform our research, development and manufacturing activities, combined with our limited inventory of materials and components and manufactured products, may cause physicians to discontinue using our products or harm our reputation, and we may be unable to reestablish relationships with such physicians in the future. Consequently, a catastrophic event at our facility could have a material adverse effect on our business, financial condition and results of operations.

Furthermore, the current lease for our manufacturing facility expires in 2024, and we may be unable to renew our lease or find a new facility on commercially reasonable terms. If we were unable or unwilling to renew at the proposed rates, relocating our manufacturing facility would involve significant expense in connection with the movement and installation of key manufacturing equipment and any necessary recertification with regulatory bodies, and we cannot assure investors that such a move would not delay or otherwise adversely affect our manufacturing activities or operating results. If our manufacturing capabilities were impaired by our move, we may not be able to manufacture and ship our products in a timely manner, which would adversely impact our business.

***We have limited experience in training and marketing and selling our products, and if we fail in our training, to increase our sales and marketing capabilities or to develop broad brand awareness in a cost effective manner, our growth will be impeded and our business will suffer.***

We have limited experience marketing and selling our products. We currently rely on our direct sales force to sell our products in targeted geographic regions, and any failure to maintain and grow our direct sales force could harm our business. The members of our direct sales force are highly trained and possess substantial technical expertise, which we believe is critical in driving adoption of TCAR. The members of our U.S. sales force are at-will employees. The loss of these personnel to competitors, or otherwise, could materially harm our business. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise in replacement personnel, our revenues and results of operations could be materially harmed.

In order to generate future growth, we plan to continue to expand and leverage our sales and marketing infrastructure to increase our physician customer base and our business. Identifying and recruiting qualified sales and marketing personnel and training them on TCAR, on applicable federal and state laws and regulations, and on our internal policies and procedures requires significant time, expense and attention. It often takes several months or more before a sales representative is fully trained and productive. Our sales force may subject us to higher fixed costs than those of companies with competing products, such as stents, that utilize independent third parties, which could place us at a competitive disadvantage. Our business may be harmed if our efforts to expand and train our sales force do not generate a corresponding increase in revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our products. Any failure to hire, develop and retain talented sales personnel, to achieve desired productivity levels in a reasonable period of time or timely reduce fixed costs, could have a material adverse effect on our business, financial condition and results of operations. Our ability to increase our customer base and achieve broader market acceptance of our products will depend to a significant extent on our ability to expand our marketing efforts. We plan to dedicate significant resources to our marketing programs. Our business may be harmed if our marketing efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our brand in a cost effective manner is critical to achieving broad acceptance of our products and penetrating new accounts. Brand promotion activities may not generate patient or physician awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the physician acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad adoption of our products.

***The market for our products is highly competitive. If our competitors are able to develop or market carotid artery disease treatments that are safer, more effective or gain greater acceptance in the marketplace, than any products we develop, our commercial opportunities will be reduced or eliminated.***

Our industry is highly competitive, subject to change and significantly affected by new product introductions and other activities of industry participants. We are initially positioning TCAR as an alternative in high risk patients to CEA and CAS. CEA has historically been performed by vascular surgeons as the primary surgical solution for carotid artery disease. The major manufacturers of products, such as patches and shunts, used in connection with CEA include LeMaitre Vascular, Getinge / Maquet, Baxter, Terumo, Gore and Edwards. Some competitors market products for use in CAS, such as peripheral access kits, stents, distal filters, guidewires, balloons and sheaths. Such companies include Abbott, Boston Scientific, Cardinal Health, Medtronic, Terumo, Gore and InspireMD. These technologies, other products that are in current clinical trials, new drugs or additional indications for existing drugs could demonstrate better safety, effectiveness, clinical results, lower costs or greater physician and patient acceptance.

We compete, or may compete in the future, against other companies which have longer operating histories, more established products and greater resources, which may prevent us from achieving significant market penetration or improved operating results. These companies enjoy several competitive advantages, including:

- Greater financial and human capital resources;
- Significantly greater name recognition;
- Established relationships with vascular surgeons, referring physicians, customers and third-party payers;
- Additional lines of products, and the ability to offer rebates or bundle products to offer greater discounts or incentives to gain a competitive advantage; and
- Established sales, marketing and worldwide distribution networks.

Because of the size of the market opportunity for the treatment of carotid artery disease, we believe potential competitors have historically dedicated and will continue to dedicate significant resources to aggressively promote their products or develop new products. New treatment options may be developed that could compete more effectively with our products due to the prevalence of carotid artery disease and the extensive research efforts and technological progress that exist within the market.

***Defects or failures associated with our products could lead to recalls, safety alerts or litigation, as well as significant costs and negative publicity.***

Our business is subject to significant risks associated with manufacture, distribution and use of medical devices that are placed inside the human body, including the risk that patients may be severely injured by or even die from the misuse or malfunction of our products caused by design flaws or manufacturing defects. In addition, component failures, design defects, off-label uses or inadequate disclosure of product-related information could also result in an unsafe condition or the injury or death of a patient. These problems could lead to a recall or market withdrawal of, or issuance of a safety alert relating to, our products and could result in significant costs, negative publicity and adverse competitive pressure. The circumstances giving rise to recalls are unpredictable, and any recalls of existing or future products could have a material adverse effect on our business, financial condition and results of operations.

We provide a limited warranty that our products are free of material defects and conform to specifications, and offer to repair, replace or refund the purchase price of defective products. As a result, we bear the risk of potential warranty claims on our products. In the event that we attempt to recover some or all of the expenses associated with a warranty claim against us from our suppliers or vendors, we may not be successful in claiming recovery under any warranty or indemnity provided to us by such suppliers or vendors and any recovery from such vendor or supplier may not be adequate.

The medical device industry has historically been subject to extensive litigation over product liability claims. Operating in the area of the neck with the brain as the end organ is dangerous and presents risks of adverse events such as arterial dissection, cranial nerve injury, stroke and death, which subject us to a greater risk of being involved in litigation than companies with products used in less critical areas of the body. We may be subject to product liability claims if our products cause, or merely appear to have caused, an injury or death, even if due to physician error. In addition, an injury or death that is caused by the activities of our suppliers, such as those that provide us with components and raw materials, or by an aspect of a treatment used in combination with our products, such as a complementary drug or anesthesia, may be the basis for a claim against us by patients, hospitals, physicians or others purchasing or using our products, even if our products were not the actual cause of such injury or death. We may choose to settle any claims to avoid fault and complication not due to failure of our products. An

adverse outcome involving one of our products could result in reduced market acceptance and demand for all of our products, and could harm our reputation and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension or delay of regulatory reviews of our premarket notifications or applications for marketing. Any of the foregoing problems could disrupt our business and have a material adverse effect on our business, financial condition and results of operations.

Although we carry product liability insurance in the United States and in other countries in which we conduct business, including for clinical trials and product marketing, we can give no assurance that such coverage will be available or adequate to satisfy any claims. Product liability insurance is expensive, subject to significant deductibles and exclusions, and may not be available on acceptable terms, if at all. If we are unable to obtain or maintain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. Defending a suit, regardless of its merit or eventual outcome, could be costly, could divert management's attention from our business and might result in adverse publicity, which could result in reduced acceptance of our products in the market, product recalls or market withdrawals.

We are required to file adverse event reports under Medical Device Reporting, or MDR, regulations with the FDA, which reports are publicly available on the FDA's website. We are required to file MDRs if our products may have caused or contributed to a serious injury or death or malfunctioned in a way that could likely cause or contribute to a serious injury or death if it were to recur. Any such MDR that reports a significant adverse event could result in negative publicity, which could harm our reputation and future sales.

***Our ability to compete depends on our ability to innovate successfully and deliver any new products in a timely manner.***

The market for our products is competitive, dynamic, and marked by rapid and substantial technological development and product innovation. New entrants or existing competitors could attempt to develop products that compete directly with ours. Demand for our products and future related products could be diminished by equivalent or superior products and technologies offered by competitors. If we are unable to innovate successfully, our products could become obsolete and our revenue would decline as our customers purchase our competitors' products.

We are currently focused on development of existing products, but may devote additional resources to research in the future. If we are unable to develop new products, applications or features due to constraints, such as insufficient cash resources, high employee turnover, inability to hire personnel with sufficient technical skills or a lack of other research and development resources, we may not be able to maintain our competitive position compared to other companies. Furthermore, many of our competitors devote a considerably greater amount of funds to their research and development programs than we do, and those that do not may be acquired by larger companies that would allocate greater resources to research and development programs. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our competitors could harm our business.

Any significant delays in our product launches may significantly impede our ability to enter or compete in a given market and may reduce the sales that we are able to generate from these products. We may experience delays in any phase of a product development, including during research and development, clinical trials, regulatory review, manufacturing and marketing. Delays in product introductions could have a material adverse effect on our business, financial condition and results of operations.

***The failure of TCAR to meet patient expectations or the occurrence of adverse events from TCAR could impair our financial performance.***

Our future success depends upon patients having an experience with TCAR that meets their expectations in order to increase physician demand for our products as a result of positive feedback, social media and word-of-mouth. Patients may be dissatisfied if their expectations of the procedure and results, among other things, are not met. Despite what we believe to be the safety profile of our products, patients may experience adverse events such as arterial restenosis or dissection, cranial nerve injury, wound complications, transient ischemic attacks, stroke, heart attack, and death. If the results of TCAR do not meet the expectations of the patients, or the patient experiences adverse events, it could discourage the patient from referring TCAR to others. Dissatisfied patients may express negative opinions through social media. Any failure to meet patient expectations and any resulting negative publicity could harm our reputation and future sales.

***We depend on our senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees could harm our business.***

Our success depends largely on the continued services of key members of our executive management team and others in key management positions. For example, the services of Erica Rogers, our Chief Executive Officer, and Lucas Buchanan, our Chief Financial Officer, are essential to driving adoption of our products, executing on our corporate strategy and ensuring the continued operations and integrity of financial reporting within our company. In addition, the services of Andrew Davis, our Executive Vice President of Global Sales and Marketing, are critical to driving the growth in sales of our products. Any of our employees may terminate their employment with us at any time. We do not currently maintain key person life insurance policies on any of our employees. If we lose one or more key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy.

In addition, our research and development programs, clinical operations and sales efforts depend on our ability to attract and retain highly skilled engineers and sales professionals. We may not be able to attract or retain qualified engineers and sales professionals in the future due to the competition for qualified personnel. We have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than we do. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees, particularly in the San Francisco Bay Area, often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, either because we are a public company or for other reasons, it may harm our ability to recruit and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

***The use, misuse or off-label use of our products may result in injuries that lead to product liability suits, which could be costly to our business.***

Our products have been approved by the FDA for the treatment of high surgical risk patients who require carotid revascularization and meet certain treatment parameters. If physicians expand the patient population in which they elect to use our products that is outside of the intended use approved by the FDA, then the use, misuse, or off-label use of our products may result in outcomes and adverse events including stroke and death, potentially leading to product liability claims. Our products are not indicated for use in all patients with carotid artery disease, and therefore cannot be marketed or advertised in the United States for certain uses without additional clearances from the FDA. However, we cannot prevent a physician from using our products for off-label applications or using components or products that are not

our products when performing TCAR. In addition, we cannot guarantee that physicians are trained by us or their peers prior to utilizing our products. Complications resulting from the use of our products off-label or use by physicians who have not been trained appropriately, or at all, may expose us to product liability claims and harm our reputation. Moreover, if the FDA determines that our promotional materials or physician training, including our paid consultants' educational materials, constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to enforcement action, including warning letters, untitled letters, fines, penalties, or seizures. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines and/or other penalties against companies for alleged improper promotion and has investigated, prosecuted, and/or enjoined several companies from engaging in off-label promotion.

In addition, if our products are defectively designed, manufactured or labeled, contains defective components or are misused, we may become subject to costly litigation initiated by physicians, hospitals or patients. Product liability claims are especially prevalent in the medical device industry and could harm our reputation, divert management's attention from our core business, be expensive to defend and may result in sizable damage awards against us. Although we maintain product liability insurance, we may not have sufficient insurance coverage for future product liability claims. We may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation, significantly increase our expenses, and reduce product sales. Product liability claims could cause us to incur significant legal fees and deductibles and claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and operating results.

***We may need substantial additional funding beyond the proceeds of this offering and may not be able to raise capital when needed, which could force us to delay, reduce or eliminate our product development programs and commercialization efforts.***

We believe that our cash and cash equivalents as of December 31, 2018, expected revenue and additional borrowings available under our term loan agreement, are not sufficient to meet our capital requirements and fund our operations for at least the next 12 months from the date the financial statements were issued. As a result, we have disclosed that there is substantial doubt about our ability to continue as a going concern. Following the offering, we do believe our cash and cash equivalents and additional borrowings available under our term loan agreement will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months following this offering. However, we have based these estimates on assumptions that may prove to be incorrect, and we could spend our available financial resources much faster than we currently expect. Our future funding requirements will depend on many factors, including:

- The degree and rate of market acceptance of TCAR and our products;
- Whether we acquire third-party companies, products or technologies;
- Repayment of debt;
- The scope and timing of investment in our sales force;
- The scope, rate of progress and cost of our current or future clinical studies;
- The cost of our research and development activities;
- The cost and timing of additional regulatory clearances or approvals;
- The costs associated with any product recall that may occur;

- The costs of attaining, defending and enforcing our intellectual property rights;
- The emergence of competing technologies or other adverse market developments; and
- The rate at which we expand internationally.

We may seek to raise additional capital through equity offerings or debt financings and such additional financing may not be available to us on acceptable terms, or at all. In addition, any additional equity or debt financing that we raise may contain terms that are not favorable to us or our stockholders. For example, if we raise funds by issuing equity or equity-linked securities, the issuance of such securities could result in dilution to our stockholders. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline, and the price per share at which we sell additional shares of our common stock, or securities convertible into or exercisable or exchangeable for shares of our common stock, in future transactions may be higher or lower than the price per share paid by investors in this offering.

In addition, the terms of debt securities issued or borrowings could impose significant restrictions on our operations including restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to pay dividends, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms, such as relinquishment or licensing of certain technologies or products that we otherwise would seek to develop or commercialize ourselves, or reserve for future potential arrangements when we might otherwise be able to achieve more favorable terms. In addition, we may be forced to work with a partner on one or more of our products or market development programs, which could lower the economic value of those programs to us.

If we are unable to obtain adequate financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay clinical trials necessary to market our products, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products. If this were to occur, our ability to grow and support our business and to respond to market challenges could be significantly limited, which could have a material adverse effect on our business, financial condition and results of operations.

***We have a significant amount of debt, which may affect our ability to operate our business and secure additional financing in the future.***

As of December 31, 2018, we had an aggregate of approximately $44.2 million in principal and interest outstanding under our term loan agreement. We must make significant quarterly payments under the loan agreement, which has diverted and will continue to divert resources from other activities. Our obligations under the term loan agreement are collateralized by substantially all of our assets, including our material intellectual property, and we are subject to customary financial and operating covenants limiting our ability to, among other things, relocate or dispose of assets, undergo a change in control, merge or consolidate, enter into certain transactions with affiliates, make acquisitions, incur debt, pay dividends, grant liens, repurchase stock and make investments, in each case subject to certain exceptions. The covenants related to the term loan agreement, as well as any future financing agreements into which we may enter, may restrict our ability to finance our operations and engage in, expand or otherwise pursue our business activities and strategies. While we have not previously breached and are not currently in breach of these or any other covenants contained in our term loan agreement, there can be no guarantee that we will not breach these covenants in the future. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under the loan agreement. If not waived, future defaults could cause all of the outstanding indebtedness under the term loan agreement to become immediately

due and payable and terminate commitments to extend further credit. If we do not have or are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, our assets could be foreclosed upon and we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern.

***We may acquire other companies or technologies, which could fail to result in a commercial product or net sales, divert our management's attention, result in additional dilution to our stockholders and otherwise disrupt our operations and harm our operating results.***

Although we currently have no agreements or commitments to complete any such transactions and are not involved in negotiations to do so, we may in the future seek to acquire or invest in businesses, applications or technologies that we believe could complement or expand our portfolio, enhance our technical capabilities or otherwise offer growth opportunities. However, we cannot assure you that we would be able to successfully complete any acquisition we choose to pursue, or that we would be able to successfully integrate any acquired business, product or technology in a cost-effective and non-disruptive manner. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment.

To date, the growth of our operations has been largely organic, and we have limited experience in acquiring other businesses or technologies. We may not be able to successfully integrate any acquired personnel, operations and technologies, or effectively manage the combined business following an acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. In addition, if an acquired business fails to meet our expectations, our operating results, business and financial condition may suffer.

***Taxing authorities may successfully assert that we should have collected or in the future should collect sales and use, gross receipts, value added or similar taxes and may successfully impose additional obligations on us, and any such assessments or obligations could adversely affect our business, financial condition and results of operations.***

We have not historically collected sales and use, gross receipts, value added or similar taxes, although we may be subject to such taxes in various jurisdictions. One or more jurisdictions may seek to impose additional tax collection obligations on us, including for past sales. A successful assertion by a state, country, or other jurisdiction that we should have been or should be collecting additional sales, use, or other taxes on our services could, among other things, result in substantial tax liabilities for past sales, create significant administrative burdens for us, discourage users from purchasing our products, or otherwise harm our business, results of operations and financial condition.

***Our ability to utilize our net operating loss carryforwards may be limited.***

As of December 31, 2018, we had U.S. federal and state net operating loss carryforwards, or NOLs, of $125.2 million and $115.8 million, respectively, which if not utilized will begin to expire in 2027 for U.S. federal purposes and 2028 for state purposes. We may use these NOLs to offset against taxable income for U.S. federal and state income tax purposes. However, Section 382 of the Internal Revenue Code of 1986, as amended, may limit the NOLs we may use in any year for U.S. federal income tax purposes in the event of certain changes in ownership of our company. A Section 382 "ownership change" generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. We have not conducted a

382 study to determine whether the use of our NOLs is impaired. We may have previously undergone an "ownership change." In addition, this offering or future issuances or sales of our stock, including certain transactions involving our stock that are outside of our control, could result in future "ownership changes." "Ownership changes" that have occurred in the past or that may occur in the future, including in connection with this offering, could result in the imposition of an annual limit on the amount of pre-ownership change NOLs and other tax attributes we can use to reduce our taxable income, potentially increasing and accelerating our liability for income taxes, and also potentially causing those tax attributes to expire unused. Any limitation on using NOLs could, depending on the extent of such limitation and the NOLs previously used, result in our retaining less cash after payment of U.S. federal and state income taxes during any year in which we have taxable income, rather than losses, than we would be entitled to retain if such NOLs were available as an offset against such income for U.S. federal and state income tax reporting purposes, which could adversely impact our operating results.

***As international expansion of our business occurs, it will expose us to market, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.***

Our long-term strategy is to increase our international presence, including securing regulatory approvals in Japan and China. We have the right to affix the CE Mark to our products, allowing us to commercialize in Europe in the future. This strategy may include establishing and maintaining physician outreach and education capabilities outside of the United States and expanding our relationships with international payers. Doing business internationally involves a number of risks, including:

- Difficulties in staffing and managing our international operations;
- Multiple, conflicting and changing laws and regulations such as tax laws, privacy laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- Reduced or varied protection for intellectual property rights in some countries;
- Obtaining regulatory clearance where required for TCAR in various countries;
- Requirements to maintain data and the processing of that data on servers located within such countries;
- Complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- Limits on our ability to penetrate international markets if we are required to manufacture our products locally;
- Financial risks, such as longer payment cycles, difficulty collecting accounts receivable, foreign tax laws and complexities of foreign value-added tax systems, the effect of local and regional financial pressures on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- Restrictions on the site-of-service for use of our products and the economics related thereto for physicians, providers and payers;
- Natural disasters, political and economic instability, including wars, terrorism, political unrest, outbreak of disease, boycotts, curtailment of trade and other market restrictions; and

- Regulatory and compliance risks that relate to maintaining accurate information and control over activities subject to regulation under the United States Foreign Corrupt Practices Act of 1977, or FCPA, U.K. Bribery Act of 2010 and comparable laws and regulations in other countries.

Any of these factors could significantly harm our future international expansion and operations and, consequently, have a material adverse effect on our business, financial condition and results of operations.

***Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or our customer's patients, or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.***

In the ordinary course of our business, we may become exposed to, or collect and store sensitive data, including procedure-based information and legally-protected health information, credit card, and other financial information, insurance information, and other potentially personally identifiable information. We also store sensitive intellectual property and other proprietary business information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology, or IT, and infrastructure, and that of our third-party billing and collections provider and other technology partners, may be vulnerable to cyber attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. We rely extensively on IT systems, networks and services, including internet sites, data hosting and processing facilities and tools, physical security systems and other hardware, software and technical applications and platforms, some of which are managed, hosted, provided and/or used by third-parties or their vendors, to assist in conducting our business. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems or infrastructure, by our workforce, others with authorized access to our systems or unauthorized persons could negatively impact operations. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third-party providers' systems, portable media or storage devices. We could also experience a business interruption, theft of confidential information or reputational damage from industrial espionage attacks, malware or other cyber-attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and becoming more prevalent in the industry. We are investing in protections and monitoring practices of our data and IT to reduce these risks and continue to monitor our systems on an ongoing basis for any current or potential threats. There can be no assurance, however, that our efforts will prevent breakdowns or breaches to our or our third-party providers' databases or systems that could adversely affect our business.

***We could be adversely affected by violations of the FCPA and similar worldwide anti-bribery laws and any investigation, and the outcome of any investigation, by government agencies of possible violations by us of the FCPA could have a material adverse effect on our business.***

The FCPA and similar worldwide anti-bribery laws prohibit companies and their intermediaries from corruptly providing any benefits to government officials for the purpose of obtaining or retaining business. We are in the process of further enhancing policies and procedures intended to help ensure compliance with these laws. In the future, we may operate in parts of the world that have experienced governmental corruption to some degree. Moreover, because of the significant role government entities play in the regulation of many foreign healthcare markets, we may be exposed to heightened FCPA and similar risks arising from our efforts to seek regulatory approval of and reimbursement for our products in such countries. We cannot assure you that our internal control policies and procedures will protect us from improper acts committed by our employees or agents. Violations of these laws, or allegations of such

violations, would significantly disrupt our business and have a material adverse effect on our business, financial condition and results of operations.

## Risks Related to Our Intellectual Property

***We may become a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell and market our products.***

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our products include components that we purchase from vendors, and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell and/or export our products or to use product names. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. The defense of these matters can be time consuming, costly to defend in litigation, divert management's attention and resources, damage our reputation and brand and cause us to incur significant expenses or make substantial payments. Vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third-party's patent or trademark or of misappropriating a third-party's trade secret.

Since patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our products. Competitors may also contest our patents, if issued, by showing the patent examiner that the invention was not original, was not novel or was obvious. In litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons. If a court agrees, we would lose our rights to those challenged patents.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees and consultants and any other partners or collaborators who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

Further, if such patents, trademarks, or trade secrets are successfully asserted against us, this may harm our business and result in injunctions preventing us from selling our products, license fees, damages and the payment of attorney fees and court costs. In addition, if we are found to willfully infringe third-party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign our products to avoid infringement.

Similarly, interference or derivation proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office, or USPTO, may be necessary to determine priority with respect to our patents, patent applications, trademarks or trademark applications. We may also become involved in other proceedings, such as reexamination, inter parties review, derivation or opposition proceedings before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing our products or using product names, which would have a significant adverse impact on our business, financial condition and results of operations.

Additionally, we may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. Furthermore, even if our patents are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business position, financial condition and results of operations.

***Our success will depend on our ability to obtain, maintain and protect our intellectual property rights.***

In order to remain competitive, we must develop, maintain and protect the proprietary aspects of our brands, technologies and data. We rely on a combination of contractual provisions, confidentiality procedures and patent, copyright, trademark, trade secret and other intellectual property laws to protect the proprietary aspects of our brands, technologies and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success will depend, in part, on preserving our trade secrets, maintaining the security of our data and know-how and obtaining and maintaining other intellectual property rights. We may not be able to obtain or maintain intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage. In addition, our trade secrets, data and know-how could be subject to unauthorized use, misappropriation, or disclosure to unauthorized parties, despite our efforts to enter into confidentiality agreements with our employees, consultants, clients and other vendors who have access to such information, and could otherwise become known or be independently discovered by third parties. Our intellectual property, including trademarks, could be challenged, invalidated, infringed, and circumvented by third parties, and our trademarks could also be diluted, declared generic or found to be infringing on other marks. If any of the foregoing occurs, we could be forced to re-brand our products, resulting in loss of brand recognition and requiring us to devote resources to advertising and marketing new brands, and suffer other competitive harm. Third parties may also adopt trademarks similar to ours, which could harm our brand identity and lead to market confusion. Failure to obtain and maintain intellectual property rights necessary to our business and failure to protect, monitor and control the use of our intellectual property rights could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the United States and other jurisdictions we depend upon may not provide sufficient protection in the future to prevent the infringement, use, violation or misappropriation of our trademarks, data, technology and other intellectual property and services, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated or otherwise violated.

We rely, in part, on our ability to obtain, maintain, expand, enforce, and defend the scope of our intellectual property portfolio or other proprietary rights, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights. The process of applying for and obtaining a patent is expensive, time consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions where protection may be commercially advantageous, or we may not be able to protect our proprietary rights at all. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. In addition, the issuance of a patent does not ensure that it is valid or enforceable, so even if we obtain patents, they may not be valid or enforceable against third parties. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. Issued patents may be challenged, narrowed, invalidated or circumvented. Decisions by courts and governmental patent agencies may introduce uncertainty in the enforceability or scope of patents owned by or licensed to us. Furthermore, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own products and practicing our own technology. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid, unenforceable or not infringed; competitors may then be able to market products and use manufacturing and analytical processes that are substantially similar to ours. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

***If we are unable to protect the confidentiality of our other proprietary information, our business and competitive position may be harmed.***

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect and some courts are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, collaborators and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other proprietary information. There can be no assurance that such third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. Despite the protections we do place on our intellectual property or other proprietary rights, monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology.

To the extent our intellectual property or other proprietary information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or

otherwise obtain and use our products or technology, or develop similar technology. Our competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our products, brand and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products and harm our business, the value of our investment in development or business acquisitions could be reduced and third parties might make claims against us related to losses of their confidential or proprietary information. Any of the foregoing could materially and adversely affect our business, financial condition and results of operations.

Further, it is possible that others will independently develop the same or similar technology or otherwise obtain access to our unpatented technology, and in such cases we could not assert any trade secret rights against such parties. Costly and time consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors obtain our trade secrets or independently develop technology similar to ours or competing technologies, our competitive market position could be materially and adversely affected. In addition, some courts are less willing or unwilling to protect trade secrets and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach.

***Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products, we may not be able to stop a competitor from marketing products that are the same as or similar to our products, which would have a material adverse effect on our business.

***We may not be able to protect our intellectual property rights throughout the world.***

A company may attempt to commercialize competing products utilizing our proprietary design, trademarks or tradenames in foreign countries where we do not have any patents or patent applications and where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting and defending patents or trademarks on our current and future products in all countries throughout the world would be prohibitively expensive. The requirements for patentability and trademarking may differ in certain countries, particularly developing countries. The laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from utilizing our inventions and trademarks in all countries outside the United States. Competitors may use our technologies or trademarks in jurisdictions where we have not obtained patent or trademark protection to develop or market their own products and further, may export otherwise infringing products to territories where we have patent and trademark protection, but enforcement on infringing activities is inadequate. These products or trademarks may compete with our products or trademarks, and our patents, trademarks or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trademarks and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents and trademarks or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent and trademarks rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and trademarks at risk of being invalidated or interpreted narrowly and our patent or trademark applications at risk, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and certain developing countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

***We may be subject to claims that we or our employees have misappropriated the intellectual property of a third party, including trade secrets or know-how, or are in breach of non-competition or non-solicitation agreements with our competitors and third parties may claim an ownership interest in intellectual property we regard as our own.***

Many of our employees and consultants were previously employed at or engaged by other medical device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other proprietary information, of these former employers or competitors.

Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property we regard as our own, based on claims that our employees or consultants have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against any other claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are

found to incorporate or be derived from the trade secrets or other proprietary information of the former employers.

An inability to incorporate technologies or features that are important or essential to our products could have a material adverse effect on our business, financial condition and results of operations, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, financial condition and results of operations.

***Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products.***

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also may affect patent litigation. These also include provisions that switched the United States from a "first-to-invent" system to a "first-to-file" system, allow third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

***The failure of third parties to meet their contractual, regulatory, and other obligations could adversely affect our business.***

We rely on suppliers, vendors, outsourcing partners, consultants, alliance partners and other third parties to research, develop, manufacture and commercialize our products and manage certain parts of our business. Using these third parties poses a number of risks, such as: (i) they may not perform to our standards or legal requirements; (ii) they may not produce reliable results; (iii) they may not perform in a timely manner; (iv) they may not maintain confidentiality of our proprietary information; (v) disputes may arise with respect to ownership of rights to technology developed with our partners; and (vi) disagreements could cause delays in, or termination of, the research, development or commercialization

of our products or result in litigation or arbitration. Moreover, some third parties are located in markets subject to political and social risk, corruption, infrastructure problems and natural disasters, in addition to country-specific privacy and data security risk given current legal and regulatory environments. Failure of third parties to meet their contractual, regulatory, and other obligations may materially affect our business.

***If our trademarks and tradenames are not adequately protected, then we may not be able to build name recognition in our markets and our business may be adversely affected.***

We rely on trademarks, service marks, tradenames and brand names to distinguish our products from the products of our competitors, and have registered or applied to register these trademarks. We cannot assure you that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources towards advertising and marketing new brands. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Certain of our current or future trademarks may become so well known by the public that their use becomes generic and they lose trademark protection. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business, financial condition and results of operations may be adversely affected.

## Risks Related to Government Regulation

***Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, could harm our business, financial condition and results of operations.***

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. In March 2010, the Affordable Care Act was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may affect our business, the Affordable Care Act:

- Imposed an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions (described in more detail below), although the effective rate paid may be lower. Through a series of legislative amendments, the tax was suspended for 2016 through 2019. Absent further legislative action, the device excise tax will be reinstated on medical device sales starting January 1, 2020;
- Established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;
- Implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- Expanded the eligibility criteria for Medicaid programs.

We do not yet know the full impact that the Affordable Care Act will have on our business. The taxes imposed by the Affordable Care Act and the expansion in the government's role in the U.S. healthcare industry may result in decreased sale of our products and, lower reimbursement by payers for our products, all of which may have a material adverse effect on our business, financial condition and results

of operations. The Trump Administration and the U.S. Congress may take further action regarding the Affordable Care Act, including, but not limited to, repeal or replacement. Most recently, the Tax Cuts and Jobs Act of 2017 was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. Additionally, all or a portion of the Affordable Care Act and related subsequent legislation may be modified, repealed or otherwise invalidated through judicial challenge, which could result in lower numbers of insured individuals, reduced coverage for insured individuals and adversely affect our business, financial condition and results of operations.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments scheduled to begin in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. It is unclear what effect new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations or cash flows.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future. Any of these could make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained. They could result in reduced demand for our products or result in additional pricing pressure. Any such reforms could have a material adverse effect on our industry generally and on our customers. Any changes of, or uncertainty with respect to, future coverage or reimbursement rates could affect demand for our products, which in turn could impact our ability to successfully commercialize our products and could have an adverse material effect on our business, financial condition and results of operations. Changes and reforms in the European Union could have similar effects.

***Changes in the CMS fee schedules may harm our revenue and operating results.***

Government payers, such as Centers for Medicare and Medicaid Services, or CMS, as well as insurers, have increased their efforts to control the cost, utilization and delivery of healthcare services. From time to time, the U.S. Congress has considered and implemented changes in the CMS fee schedules in conjunction with budgetary legislation. Reductions of reimbursement by Medicare or Medicaid for procedures that use our products or changes in policy regarding coverage of these procedures, such as adding requirements for payment, or prior authorizations, may be implemented from time to time. Reductions in the reimbursement rates and changes in payment policies of other third-party payers may occur as well. Similar changes in the past have resulted in reduced payments for procedures that use medical device products as well as added costs and have added more complex regulatory and administrative requirements. Further changes in federal, state, local and third-party payer regulations or policies may have a material adverse impact on the demand for our products and on our business. Actions by agencies regulating insurance or changes in other laws, regulations, or policies may also have a material adverse effect on our business, financial condition and results of operations.

***If we fail to comply with broad based healthcare and other governmental regulations, we could face substantial fines and penalties and our business, results of operations and financial condition could be adversely affected.***

The products we offer are highly regulated, and there can be no assurance that the regulatory environment in which we operate will not change significantly and adversely in the future. Our arrangements with physicians, hospitals and medical centers will expose us to broadly applicable fraud and abuse and other laws and regulations that may restrict the financial arrangements and relationships through which we market, sell and distribute our products. Our employees, consultants, and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements. Federal and state healthcare laws and regulations that may affect our ability to conduct business, include, without limitation:

- Federal and state laws and regulations regarding billing and claims payment applicable to TCAR and regulatory agencies enforcing those laws and regulations;
- FDA prohibitions against the advertisement, promotion and labeling of our products for off-label uses, or uses outside the specific indications approved by the FDA;
- The federal Anti-Kickback Statute, which broadly prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the CMS programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $100,000 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines of up to $100,000 and imprisonment of up to 10 years. Similarly, violations can result in mandatory exclusion from participation in government healthcare programs, including Medicare and Medicaid;
- The federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government. These laws can apply to manufacturers who provide inaccurate information on coverage, coding, and reimbursement of their products to persons who bill third-party payers. Private individuals can bring False Claims Act “qui tam” actions, on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties ranging from $11,181 to $22,363 for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- Federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making, or causing to be made, false statements relating to healthcare matters;
- The federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- The FCPA, the U.K. Bribery Act of 2010, and other local anti-corruption laws that apply to our international activities;

- The federal Physician Payment Sunshine Act, or Open Payments, created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or Affordable Care Act, and its implementing regulations, which requires manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to licensed physicians, certain other healthcare professionals, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations, to report annually ownership and investment interests held by physicians and their immediate family members. Applicable manufacturers are required to submit annual reports to CMS. Our failure to submit required information on time may result in civil monetary penalties of $11,052 per failure up to an aggregate of $165,786 per year (or up to an aggregate of $1.105 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information; HIPAA also created criminal liability for knowingly and willfully falsifying or concealing a material fact or making a materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Failure to comply with the HIPAA privacy and security standards when applicable can result in civil monetary penalties up to $55,910 per violation, not to exceed $1.68 million per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or imprisonment. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages on behalf of residents of his or her state; and

- Analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers or patients; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers, foreign and state laws, including the E.U. General Data Protection Regulation, or GDPR, governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions or safe harbors, it is possible that some of our activities, such as stock-option compensation paid to physicians, could be subject to challenge under one or more of such laws. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments.

The growth of our business and sales organization and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and administrative penalties, damages, fines, imprisonment, for individuals, exclusion from participation in government programs, such as Medicare and Medicaid, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

***If we fail to obtain and maintain necessary regulatory clearances or approvals for our products, or if clearances or approvals for future products and indications are delayed or not issued, our commercial operations would be harmed.***

Our products are subject to extensive regulation by the FDA in the United States and by regulatory agencies in other countries where we do business. Government regulations specific to medical devices are wide ranging and govern, among other things:

- Product design, development and manufacture;
- Laboratory, preclinical and clinical testing, labeling, packaging, storage and distribution;
- Premarketing clearance or approval;
- Record keeping;
- Product marketing, promotion and advertising, sales and distribution; and
- Post marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals.

Before a new medical device, or a new intended use for an existing product, can be marketed in the United States, a company must first submit and receive either 510(k) clearance pursuant to Section 510 (k) of the Food, Drug and Cosmetic Act, or the FDCA, or approval of a premarket approval, or PMA, application from the FDA, unless an exemption applies.

In many cases, the process of obtaining PMA approval, which was required for the ENROUTE stent, is much more rigorous, costly, lengthy and uncertain than the 510(k) clearance process. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, in order to clear the proposed device for marketing. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based on extensive data, including technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices for which the 510(k) process cannot be used and that are deemed to pose the greatest risk. Modifications to products that are approved through a PMA application generally need prior FDA approval of a PMA supplement. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k), or such modification may put the device into class III and require PMA approval. The FDA's 510(k) clearance process usually takes from three to

12 months, but may last longer. The process of obtaining a PMA generally takes from one to three years, or even longer, from the time the PMA is submitted to the FDA until an approval is obtained. Any delay or failure to obtain necessary regulatory approvals or clearances would have a material adverse effect on our business, financial condition and results of operations.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- Our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;
- The disagreement of the FDA or the applicable foreign regulatory body with the design, conduct or implementation of our clinical trials or the analyses or interpretation of data from pre-clinical studies or clinical trials;
- Serious and unexpected adverse device effects experienced by participants in our clinical trials;
- The data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required;
- Our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- An advisory committee, if convened by the applicable regulatory authority, may recommend against approval of our application or may recommend that the applicable regulatory authority require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions, or even if an advisory committee, if convened, makes a favorable recommendation, the respective regulatory authority may still not approve the product;
- The applicable regulatory authority may identify significant deficiencies in our manufacturing processes, facilities or analytical methods or those of our third party contract manufacturers;
- The potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval; and
- The FDA or foreign regulatory authorities may audit our clinical trial data and conclude that the data is not sufficiently reliable to support approval or clearance.

Similarly, regulators may determine that our financial relationships with our principal investigators resulted in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial itself. Even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Moreover, the FDA and European Union regulatory authorities strictly regulate the labeling, promotion and advertising of our products, including comparative and superiority claims vis a vis competitors' products, that may be made about products.

As a condition of approving a PMA application, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device. As a part of our PMA approval, we agreed with the FDA to conduct a post-approval study at a minimum of 30 sites in the United States to evaluate the safety and effectiveness of our products in at least 600 subjects. Thereafter, the product labeling must be updated and submitted in a PMA supplement, including any adverse event data, from the post-approval study. Failure to conduct the post-approval study in compliance with applicable regulations or to timely complete required post-approval

studies or comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would harm our business.

In addition, we are required to investigate all product complaints we receive, and timely file reports with the FDA, including MDRs that require that we report to regulatory authorities if our products may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not submitted in a timely manner, regulators may impose sanctions and we may be subject to product liability or regulatory enforcement actions, including warning letters, untitled letters, fines, civil penalties, recalls, seizures, operating restrictions, denial of requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products, withdrawal of current 510(k) clearances or premarket approvals and narrowing of approved or cleared product labeling, all of which could harm our business. In addition, the FDA may provide notice of and conduct additional inspections, such as "for cause" inspections, of our business, sites and facilities as part of its review process. We recently identified the need to implement corrective actions to our compliant handling procedures, which may have caused a delay in timely submission of 20 MDR reports to the FDA since we began commercialization in 2015. As of March 15, 2019, we had filed 60 MDR reports with the FDA for adverse events including stroke, arterial dissection, stent thrombosis and wound complications.

If we initiate a correction or removal action for our products to reduce a significant risk to health posed by our products, we would be required to submit a publicly available correction and removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our products. Furthermore, the submission of these reports could be used by competitors against us and cause physicians to delay or cancel prescriptions, which could harm our reputation.

The FDA and the Federal Trade Commission, or FTC, also regulate the advertising, promotion and labeling of our products to ensure that the claims we make are consistent with our regulatory clearances and approvals, that there is adequate and reasonable scientific data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including adverse publicity, warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

The FDA and state authorities have broad investigation and enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- Adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;
- Repair, replacement, refunds, recalls, termination of distribution, administrative detention or seizure of our products;
- Operating restrictions, partial suspension or total shutdown of production;
- Denial of our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;
- Withdrawal of 510(k) clearance or premarket approvals that have already been granted; and
- Criminal prosecution.

If any of these events were to occur, our business and financial condition could be harmed. In addition, the FDA's and other regulatory authorities' policies may change and additional government

regulations may be enacted that could prevent, limit or delay regulatory approval of our products. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of medical devices and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, financial condition and results of operations.

***Our clinical trials may fail to demonstrate competent and reliable evidence of the safety and effectiveness of our products, which would prevent or delay commercialization of our products in development.***

We may be required to conduct clinical studies that demonstrate competent and reliable evidence that our products are safe and effective before we can commercialize our products. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot be certain that our planned clinical trials or any other future clinical trials will be successful. In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our products for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our products. Even if regulatory approval is secured for any of our products, the terms of such approval may limit the scope and use of our products, which may also limit their commercial potential.

***Material modifications to our products may require new 510(k) clearances, premarket approval, or CE Marks, or may require us to recall or cease marketing our products until new clearances or approvals are obtained.***

Material modifications to the intended use or technological characteristics of our products will require new 510(k) clearances, premarket approvals or CE Marks prior to implementing the modifications, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Furthermore, changes to our manufacturing facility or supplier of components used in our products require prior FDA approval of a PMA supplement. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA cleared device that would significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or approval of a PMA supplement. We may not be able to obtain additional 510(k) clearances or premarket approvals for new products or for modifications to, or additional indications for, our products in a timely fashion, or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We have made modifications to our products in the past that we believe do not require additional clearances or approvals, and we may make additional modifications in the future. If the FDA or an EU Notified Body disagrees and requires new clearances or approvals for any of these modifications, we may be required to recall and to stop selling or marketing our products as modified, which could harm our operating results and require us to redesign our products. In these circumstances, we may be subject to significant enforcement actions.

***If we, or our suppliers, fail to comply with the FDA's QSR or the European Union's Medical Device Directive, our manufacturing or distribution operations could be delayed or shut down and our revenue could suffer.***

Our manufacturing and design processes and those of our third-party component suppliers are required to comply with the FDA's Quality System Regulation, or QSR, and the European Union's Medical

Device Directive, or MDD, both of which cover procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. We are also subject to similar state requirements and licenses, and to ongoing ISO 13485 compliance in our operations, including design, manufacturing, and service, to maintain our CE Mark. In addition, we must engage in extensive recordkeeping and reporting and must make available our facilities and records for periodic unannounced inspections by governmental agencies, including the FDA, state authorities, EU Notified Bodies and comparable agencies in other countries. If we fail a regulatory inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take timely and adequate corrective action in response to an adverse regulatory inspection could result in, among other things, a shutdown of our manufacturing or product distribution operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our device, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our products and cause our revenue to decline.

We are registered with the FDA as a medical device specifications developer and manufacturer. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Public Health, or CDPH, and our Notified Body to determine our compliance with the QSR and other regulations at both our design and manufacturing facilities, and these inspections may include the manufacturing facilities of our suppliers. These inspections may be initiated as a result of concerns regarding the safety of our products or the components thereof.

We can provide no assurance that we will continue to remain in material compliance with the QSR or MDD. If the FDA, CDPH or our notified body in the European Union, the British Standards Institution, or BSI, inspect any of our facilities and discover compliance problems, we may have to cease manufacturing and product distribution until we can take the appropriate remedial steps to correct the audit findings. Taking corrective action may be expensive, time consuming and a distraction for management and if we experience a delay at our manufacturing facility we may be unable to produce our products, which would harm our business.

With the transition from the MDD to the new European Union Medical Device Regulation, or MDR, notified bodies are required to seek designation to operate as conformity assessment authorities under the new law, which is effective in May 2020. Should our notified body fail to obtain such designation or the scope of their designation does not include our product category, then our ability to apply the CE mark and commercialize in the European Union may be interrupted. Identification and engagement of a new and properly designated notified body is a time consuming process that may require comprehensive quality system audits and new conformity assessment certifications for our products.

***The impact of the new EU Medical Device Regulation may be costly and disruptive to our business.***

In 2017, the European Union released new regulations to ensure patient safety with the use of pharmaceuticals, medical devices and in-vitro diagnostics that will go into effect over a three-year period from 2020 to 2022. The new regulations replace predecessor directives and emphasize a global convergence of regulations. Major changes include:

- Reclassification of some products;
- Greater emphasis on clinical data;
- Data transparency, including publication of clinical trial data and safety summaries;
- Defined content and structure for technical files to support registration;

- Unique device identification system;
- Greater burden on post-market surveillance and clinical follow-up;
- Reduction of adverse event reporting time from 30 to 15 days after the event; and
- More power to notified bodies.

Complying with these new regulations may result in Europe being less attractive as a "first market" destination. Marketing authorization timelines will become more protracted and the costs of operating in Europe will increase. A significantly more costly path to regulatory compliance is anticipated. Adjusting to the new Medical Device Regulation may prove to be costly and disruptive to our business.

***Our products may in the future be subject to product recalls that could harm our reputation.***

The FDA and similar governmental authorities in other countries have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or defects in design or manufacture. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design or labeling defects. Recalls of our products would divert managerial attention, be expensive, harm our reputation with customers and harm our financial condition and results of operations. A recall announcement would also negatively affect our stock price.

***Compliance with environmental laws and regulations could be expensive, and failure to comply with these laws and regulations could subject us to significant liability.***

Our research and development and manufacturing operations involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive and noncompliance could result in substantial liabilities, fines and penalties, personal injury and third-party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and operating results.

## Risks Related to This Offering

***Our common stock has never been publicly traded, and we expect that the price of our common stock will fluctuate substantially.***

Before this initial public offering, there has been no public market for our common stock. An active public trading market may not develop after completion of this offering or, if developed, may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other products, technologies or businesses using our shares as consideration. Furthermore, although we have been approved to list our common stock on the Nasdaq Stock Market, even if listed, there can be no guarantee that we will continue to satisfy the continued listing standards of the Nasdaq Stock Market. If we fail to satisfy the continued listing standards, we could be de-listed, which would have a negative effect on the price of our common stock.

The initial public offering price for our common stock was determined through negotiations between the underwriters and us and may vary substantially from the market price of our common stock following this offering. This price may not reflect the public trading price of our common stock following this offering, which will be affected by a number of factors, including:

- Changes in analysts' estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' estimates;
- Quarterly variations in our or our competitors' results of operations;
- Periodic fluctuations in our revenue, which could be due in part to the way in which we recognize revenue;
- The financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- General market conditions and other factors unrelated to our operating performance or the operating performance of our competitors;
- Changes in reimbursement by current or potential payers;
- Changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;
- Actual or anticipated changes in regulatory oversight of our products;
- The results of our clinical trials;
- The loss of key personnel, including changes in our board of directors and management;
- Product recalls or other problems associated with our products;
- Legislation or regulation of our market;
- Lawsuits threatened or filed against us, including litigation by current or former employees alleging wrongful termination, sexual harassment, whistleblower or other claims;
- The announcement of new products or product enhancements by us or our competitors;
- Announced or completed acquisitions of businesses or technologies by us or our competitors;
- Announcements related to patents issued to us or our competitors and related litigation; and
- Developments in our industry.

In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of listed companies. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance. These fluctuations may be even more pronounced in the trading market for our common stock shortly following this offering. If the market price of shares of our common stock after this offering does not ever exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment.

In addition, in the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and harm our business, results of operations, financial condition and reputation. These factors may materially and adversely affect the market price of our common stock.

***If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our share price and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our shares or change their opinion of our business, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

***A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.***

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lapse of lock-up and other legal restrictions on resale discussed in this prospectus, the trading price of our common stock could decline. Upon the completion of this offering, based on the number of shares of our capital stock outstanding as of December 31, 2018, we will have a total of 30,228,959 shares of our common stock outstanding, assuming the conversion of all of our outstanding shares of convertible preferred stock and the automatic net exercise of outstanding warrants to purchase shares of convertible preferred stock and common stock as of December 31, 2018, in each case into common stock upon completion of this offering, at the initial public offering price of $20.00 per share. Of these shares, all of the shares of common stock sold in this offering will be freely tradable, without restriction, in the public market immediately after the offering. Each of our directors and officers and substantially all of our other stockholders and option holders have entered into a lock-up agreement with the underwriters that restricts their ability to sell or transfer their shares. The lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus. The underwriters, however, may, in their sole discretion, waive the contractual lock-up prior to the expiration of the lock-up agreements. After the lock-up agreements expire, based on shares outstanding as December 31, 2018, 24,228,959 shares of common stock, plus any shares purchased in this offering by our existing investors, will be eligible for sale in the public market, of which 396,788 shares will be held by directors, 22,723,499 by executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, and various vesting agreements. In addition, 4,364,377 shares of common stock that are subject to outstanding options as of December 31, 2018 and an additional 654,792 shares of common stock to be granted as of the effectiveness of the registration statement of which this prospectus forms a part, will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements, the lock-up agreements and Rules 144 and 701 under the Securities Act. We intend to file a registration statement on Form S-8 under the Securities Act covering all of the shares of common stock subject to options outstanding and reserved for issuance under our stock plans. This registration statement will become effective immediately upon filing, and shares covered by this registration statement will be eligible for sale in the public markets, subject to Rule 144 limitations applicable to affiliates and any lock-up agreements described above. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of an aggregate of 22,800,622 shares of our outstanding common stock as of December 31, 2018, will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.

***Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.***

As of December 31, 2018, our directors, officers and each stockholder holding 5% or more of our outstanding common stock and their affiliates beneficially owned approximately 86.9% of our outstanding common stock in the aggregate, assuming the exercise of all outstanding options and automatic net exercise of all outstanding warrants at the initial public offering price of $20.00 per share. We expect that immediately following completion of this offering, our directors, officers and each stockholder holding 5% or more of our outstanding common stock and their affiliates will beneficially own approximately 71.8% of the outstanding shares of our common stock in the aggregate, based on the number of shares outstanding as of December 31, 2018 and assuming the exercise of all options and automatic net exercise of all warrants. In addition, entities affiliated with Warburg Pincus & Co. hold over fifty percent of our capital stock prior to this offering and following the offering we are required to nominate and use commercially reasonable efforts to have a number of individuals proportionate to the number of shares of common stock held by them compared to the number of shares of common stock outstanding, designated by each of Warburg Pincus & Co. and entities affiliated with the Vertical Group, L.P., elected to the board of directors. As a result, the above stockholders, if they act together, and Warburg Pincus & Co., acting alone, will be able to exert significant influence over the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. We have not elected under the rules of the Nasdaq Stock Market to take advantage of the "controlled company" exemption to opt out of any corporate governance requirements, but this concentration of ownership may have the effect of delaying or preventing a change in control, might adversely affect the market price of our common stock and may not be in the best interests of our other stockholders.

***We will have broad discretion in the use of net proceeds from this offering.***

The principal purpose of this offering is to provide additional capital to us. We intend to use the net proceeds from this offering to expand our sales force and operations, increase our research and development activities, conduct or sponsor clinical studies and trials, promote international expansion, and provide for working capital and other general corporate purposes. We may also use a portion of the net proceeds from this offering for the acquisition of, or strategic investment in, technologies, solutions or businesses that complement our business, although we have no present commitments or agreements to enter into any such acquisition or investment. Within these categories, our management will have broad discretion over the use and investment of the net proceeds of this offering, and accordingly, investors in this offering will need to rely upon the judgment of our management with respect to the use of proceeds with only limited information concerning management's specific intentions. We will not receive any proceeds from the sale of shares to be offered by the selling stockholders.

***We have disclosed that there is substantial doubt about our ability to continue as a going concern.***

In Note 1 to our consolidated financial statements, we disclose that there is substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm issued an explanatory paragraph in its report on our consolidated financial statements as of and for the year ended December 31, 2018. If we are unable to obtain sufficient funding, we could be forced to delay, reduce or eliminate all of our research and development programs, future research and development efforts and ongoing trials, and our financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. After the completion of this offering, future financial statements may disclose substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.

***We have previously identified two material weaknesses in our internal control over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, which may result in material misstatements of our financial statements or cause us to fail to meet our periodic reporting obligations.***

Prior to this offering, we were a private company and had limited accounting and financial reporting personnel and other resources with which to address our internal controls and procedures. In connection with the audit of our consolidated financial statements for the year ended December 31, 2017, we and our independent registered public accounting firm identified two material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

We determined that we had a material weakness because we did not maintain a sufficient complement of personnel with an appropriate degree of knowledge, experience, and training, commensurate with our accounting and reporting requirements. As a result, there were a number of post initial close adjustments that were material to the financial statements.

The second material weakness relates to the fact that we did not appropriately design and implement controls over the review and approval of manual journal entries and the related supporting journal entry calculations, resulting in inappropriate segregation of duties over manual journal entries. This material weakness could result in a misstatement of account balances or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected.

With the oversight of senior management and our audit committee, we executed the implementation of remediation steps in 2018. These efforts focused on (i) the hiring of personnel with technical accounting and financial reporting experience and (ii) the implementation of improved accounting and financial reporting procedures and systems to improve the completeness, timeliness and accuracy of our financial reporting and disclosures including the assessment of more judgmental areas of accounting. We believe the measures described above will remediate the material weaknesses identified and strengthen our internal control over financial reporting. These improvements to our internal control infrastructure were implemented in the fourth quarter of 2018, and were ongoing during the preparation of our financial statements for the year ended December 31, 2018. As such, the remediation initiatives outlined above were not sufficient to fully remediate the material weaknesses in internal control over financial reporting as discussed above. We are committed to continuing to improve our internal control processes and will continue to diligently and vigorously review our financial reporting controls and procedures.

While we continue to implement our plan to remediate the material weaknesses, we cannot predict the success of such plan or the outcome of our assessment of these plans at this time. We can give no assurance that this implementation will remediate these deficiencies in internal control or that additional material weaknesses or significant deficiencies in our internal control over financial reporting will not be identified in the future. Our failure to implement and maintain effective internal control over financial reporting could result in errors in our financial statements that could result in a restatement of our financial statements, causing us to fail to meet our reporting obligations.

***As a result of becoming a public company, we will be obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our ordinary shares.***

We will be required, pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, to furnish a report by management on the effectiveness of our internal control over financial reporting for the first fiscal year beginning after the effective date of this offering. This assessment will need to include

disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our first annual report required to be filed with the SEC following the date we are no longer an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. At such time as we are required to obtain auditor attestation, if we then have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered accounting firm.

We are beginning the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404, and we may not be able to complete our evaluation, testing and any required remediation in a timely fashion. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404.

During our evaluation of our internal control, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our ordinary shares could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

***We are an “emerging growth company” and a "smaller reporting company" and we cannot be certain if the reduced disclosure requirements applicable to us will make our common stock less attractive to investors.***

We currently qualify as an “emerging growth company” under the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions from reporting requirements that are applicable to other public companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. To the extent that we continue to qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, after we cease to qualify as an emerging growth company, we will continue to be permitted to make certain reduced disclosures in our periodic reports and other documents that we file with the SEC. We cannot predict if investors will find our common stock less attractive to the extent we rely on available exemptions. If some investors do find our common stock less attractive, there may be a less active trading market for our common stock and our stock price may be more volatile or may decline.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of the completion of this offering, (2) the last day of the fiscal year in which we have total annual revenue of more than $1.07 billion, (3) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates

exceeds $700 million as of the prior June 30th, and (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

***Anti-takeover provisions in our amended and restated certificate of incorporation and bylaws, and Delaware law, could discourage a change in control of our company or a change in our management.***

Our amended and restated certificate of incorporation and bylaws, as amended and restated in connection with this offering, will contain provisions that might enable our management to resist a takeover. These provisions include:

- A classified board of directors;
- Advance notice requirements applicable to stockholders for matters to be brought before a meeting of stockholders and requirements as to the form and content of a stockholders' notice;
- A supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and bylaws;
- The right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer;
- Allowing stockholders to remove directors only for cause;
- A requirement that the authorized number of directors may be changed only by resolution of the board of directors;
- Allowing all vacancies, including newly created directorships, to be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum, except as otherwise required by law;
- A requirement that our stockholders may only take action at annual or special meetings of our stockholders and not by written consent;
- Limiting the forum to Delaware for certain litigation against us; and
- Limiting the persons that can call special meetings of our stockholders to our board of directors, the chairperson of our board of directors, the chief executive officer or the president, in the absence of a chief executive officer.

These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder. See "Description of Capital Stock."

***Our amended and restated certificate of incorporation and bylaws will provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' abilities to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our amended and restated certificate of incorporation and bylaws will provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum, to the fullest extent

permitted by law, for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against the company or any director or officer of the company arising pursuant to any provision of the Delaware General Corporation Law, (4) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or bylaws, or (5) any other action asserting a claim that is governed by the internal affairs doctrine shall be the Court of Chancery of the State of Delaware or federal court located within the State of Delaware if the Court of Chancery does not have jurisdiction, in all cases subject to the court's having jurisdiction over indispensable parties named as defendants. A complaint asserting a cause of action under the Securities Act may be brought in state or federal court. With respect to the Securities Exchange Act of 1934, or Exchange Act, only claims brought derivatively under the Exchange Act would be subject to the forum selection clause described above. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation and bylaws has been challenged in legal proceedings, and it is possible that, in connection with any action, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation and bylaws to be inapplicable or unenforceable in such action. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors and officers. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation and bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition and operating results. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

***We have not paid dividends in the past and do not expect to pay dividends in the future, and, as a result, any return on investment may be limited to the value of our stock.***

We have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future. The payment of dividends will depend on our earnings, capital requirements, financial condition, prospects for future earnings and other factors our board of directors may deem relevant. In addition, our loan agreement limits our ability to, among other things, pay dividends or make other distributions or payments on account of our common stock, in each case subject to certain exceptions. If we do not pay dividends, our stock may be less valuable because a return on your investment will only occur if our stock price appreciates and you then sell our common stock.

***If we are unable to implement and maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected.***

Our chief financial officer has not been the chief financial officer of a publicly traded company and our chief executive officer has not been the chief executive officer of a publicly traded company. Neither has been involved in the transition of a private company to a public company through an initial public offering. As a public company, we will be required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. We will be required, pursuant to Section 404, to evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our second annual report after the completion of this offering, provide a management report on the internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our first annual report required to be filed with the SEC following the date we are no longer an "emerging growth company," as defined in the JOBS Act. At such time as we are required to obtain auditor attestation, if we then have a material weakness, we would

receive an adverse opinion regarding our internal control over financial reporting from our independent registered accounting firm. If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We are implementing the process and documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion.

If we have material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We are beginning the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404, and we may not be able to complete our evaluation, testing and any required remediation in a timely fashion. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404.

During our evaluation of our internal control, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our ordinary shares could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which could require additional financial and management resources and could result in fines, trading suspensions or other remedies. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

***New investors purchasing our common stock will experience immediate and substantial dilution.***

Our initial public offering price is substantially higher than the book value per share of our common stock. If you purchase common stock in this offering, you will incur immediate dilution of $16.84 in net tangible book value per share of common stock, based on an initial public offering price of $20.00 per share. In addition, the number of shares available for issuance under our stock option and employee stock purchase plans will increase annually without further stockholder approval. Investors will incur additional dilution upon the exercise of stock options and warrants. See “Dilution.”

# CAUTIONARY NOTES REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology.

These forward-looking statements include, but are not limited to, statements about:

- our plans to conduct further clinical trials;
- our plans and expected timeline related to our products, or developing new products, to address additional indications or otherwise;
- the expected use of our products by physicians;
- our ability to obtain, maintain and expand regulatory clearances for our products and any new products we create;
- the expected growth of our business and our organization;
- our expected uses of the net proceeds from this offering;
- our expectations regarding government and third-party payer coverage and reimbursement;
- our ability to retain and recruit key personnel, including the continued development of a sales and marketing infrastructure;
- our ability to obtain an adequate supply of materials and components for our products from our third-party suppliers, most of whom are single-source suppliers;
- our ability to manufacture sufficient quantities of our products with sufficient quality;
- our ability to obtain and maintain intellectual property protection for our products;
- our ability to expand our business into new geographic markets;
- our compliance with extensive Nasdaq requirements and government laws, rules and regulations both in the United States and internationally;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our need for, or ability to obtain, additional financing;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- our ability to identify and develop new and planned products and/or acquire new products; and
- developments and projections relating to our competitors or our industry.

We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this prospectus may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under "Risk Factors" and elsewhere in this prospectus. Potential investors are urged to consider these factors carefully in evaluating the forward-looking statements.

These forward-looking statements speak only as of the date of this prospectus. We assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

# MARKET, INDUSTRY AND OTHER DATA

This prospectus contains estimates and information concerning our industry, including market size and growth rates of the markets in which we participate, that are based on industry publications and reports. We relied on industry, market data, peer reviewed journals, formal presentations at medical society meetings and other sources, including a report from Modus Health. We also rely on our own research and estimates in this prospectus. This information involves a number of assumptions and limitations, and you are cautioned not to give undue weight to these estimates. We have not independently verified the accuracy or completeness of the data contained in these industry publications and reports. We also rely on independent third party sources for procedure data in the United States, as well as publicly available data.

Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information, including those described in “Risk Factors.” These and other factors could cause results to differ materially from those expressed in these publications and reports.

# DIVIDEND POLICY

We have never declared or paid, and do not anticipate declaring or paying, any cash dividends on any of our capital stock. We do not anticipate paying any dividends in the foreseeable future, and we currently intend to retain all available funds and any future earnings for use in the operation of our business, to finance the growth and development of our business and for future repayment of debt. Future determinations as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then-existing conditions, including our operating results, financial condition, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. In addition, our term loan agreement limits our ability to pay dividends or make other distributions or payments on account of our common stock, in each case subject to certain exceptions.

# USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately $109.1 million based upon an initial public offering price of $20.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, net of actual payments of offering expenses of $233,000 as of December 31, 2018. We will not receive any net proceeds from the sale of shares of common stock by the selling stockholders if the underwriters exercise their option to purchase additional shares, which are expected to be approximately $16.7 million if such option is exercised in full.

The principal purpose of this offering is to provide us with additional capital. We intend to use the net proceeds from this offering to expand our sales force and operations, increase our research and development activities, conduct or sponsor clinical studies and trials, expand internationally, and provide for working capital and other general corporate purposes. We may use a portion of the net proceeds to acquire complementary products, technologies, intellectual property or businesses; however, we currently do not have any agreements or commitments to complete any such transactions and are not involved in negotiations regarding such transactions.

As of the date of this prospectus, we cannot specify with certainty the specific allocations or all of the particular uses for the net proceeds to be received upon the completion of this offering. Accordingly, our management and board of directors will have broad discretion in the application and specific allocations of the net proceeds, and investors will be relying on the judgment of our management and board of directors regarding the application of the proceeds of this offering.

These expected uses represent our current intentions based upon our present plans and market conditions. The amounts we actually expend in these areas, and the timing thereof, may vary significantly from our current intentions and will depend upon a number of factors, including future sales growth, success of research and product development efforts, cash generated from future operations and actual expenses to operate our business.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in short-term, investment grade, interest bearing instruments, money market funds, certificates of deposit, commercial paper and U.S. government securities.

# CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2018 on:

- an actual basis, after giving effect to the reverse stock split;
- a pro forma basis, giving effect to (i) the conversion of all of our outstanding shares of our convertible preferred stock into shares of our common stock, (ii) the automatic net exercise of outstanding warrants to purchase shares of convertible preferred stock and common stock into shares of common stock, at the initial public offering price of $20.00 per share, and the reclassification of our convertible preferred stock warrant liability to stockholders' equity; and (iii) the filing and effectiveness of our amended and restated certificate of incorporation, in each case, immediately upon completion of this offering; and
- a pro forma as adjusted basis, giving effect to (i) the pro forma adjustments set forth above and (ii) the sale and issuance of 6,000,000 shares of common stock by us in this offering, based upon the initial public offering price of $20.00 per share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, net of actual payments of offering expenses of $233,000 as of December 31, 2018.

You should read this table together with the section of this prospectus entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes thereto included elsewhere in this prospectus.

| | As of December 31, 2018 | | |
|---|---|---|---|
| *(in thousands, except share data)* | **Actual** | **Pro Forma** | **Pro Forma As Adjusted** |
| Cash and cash equivalents | $ 24,990 | $ 24,990 | $ 134,073 |
| Long-term debt | 44,201 | 44,201 | 44,201 |
| Convertible preferred stock warrant liability | 16,091 | — | — |
| Convertible preferred stock issuable in series, $0.001 par value; 24,069,615 shares authorized, 21,233,190 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted | 105,235 | — | — |
| Stockholders' equity (deficit): | | | |
| Preferred stock, $0.001 par value; no shares authorized, issued and outstanding, actual; 5,000,000 shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted | — | — | — |
| Common stock, $0.001 par value; 29,879,220 shares authorized, 1,135,310 shares issued and outstanding, actual; 100,000,000 shares authorized pro forma and pro forma as adjusted, 24,228,959 shares issued and outstanding, pro forma; and 30,228,959 shares issued and outstanding, pro forma as adjusted | 1 | 24 | 30 |
| Additional paid-in capital | 4,557 | 125,860 | 234,704 |
| Accumulated deficit | (139,111) | (139,111) | (139,111) |
| Total stockholders' equity (deficit) | (134,553) | (13,227) | 95,623 |
| Total capitalization | $ 30,974 | $ 30,974 | $ 139,824 |

The number of shares of common stock that will be outstanding after this offering is based on 24,228,959 shares of common stock outstanding, assuming the conversion of all of our outstanding shares of convertible preferred stock and the automatic net exercise of outstanding warrants to purchase shares of convertible preferred stock and common stock as of December 31, 2018, in each case into common stock upon completion of this offering, at the initial public offering price of $20.00 per share, and excludes:

- 4,364,377 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock outstanding as of December 31, 2018, with a weighted-average exercise price of $3.79 per share;
- 32,950 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock granted after December 31, 2018, with a weighted-average exercise price of $11.29 per share; and
- 2,775,939 shares of common stock reserved for future grants under our stock-based compensation plans, consisting of:
    - 24,939 shares of common stock reserved for future grants under our 2007 Stock Plan, which shares will be added to the shares to be reserved under our 2019 Equity Incentive Plan;
    - 2,317,000 shares of common stock reserved for future grants under our 2019 Equity Incentive Plan, including 654,792 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock granted to certain of our executive officers, directors and new employees pursuant to our 2019 Equity Incentive Plan, with a grant date of April 3, 2019, and with an exercise price equal to $20.00 per share; and
    - 434,000 shares of common stock reserved for future issuance under our 2019 Employee Stock Purchase Plan.

# DILUTION

If you invest in our common stock in this offering, your interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock in this offering and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

As of December 31, 2018, our historical net tangible book value (deficit) was $(135.5) million, or $(119.35) per share of common stock. Historical net tangible book value (deficit) per share represents our total tangible assets (total assets less deferred offering costs) less total liabilities, less convertible preferred stock, divided by the number of our shares of common stock outstanding as of December 31, 2018.

As of December 31, 2018, our pro forma net tangible book value (deficit) was $(14.2) million, or $(0.59) per share of common stock. Pro forma net tangible book value before the issuance and sale of shares in this offering represents the amount of our total tangible assets (total assets less deferred offering costs) reduced by the amount of our total liabilities and divided by the total number of shares of our common stock outstanding as of December 31, 2018, assuming the conversion of all of our outstanding shares of convertible preferred stock into shares of our common stock, the automatic net exercise of outstanding warrants to purchase shares of convertible preferred stock and common stock into shares of common stock, at the initial public offering price of $20.00 per share, and the reclassification of our convertible preferred stock warrant liability to stockholders' equity, in each case, immediately upon completion of this offering.

After giving further effect to the sale of 6,000,000 shares of our common stock in this offering at the initial public offering price of $20.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, net of actual payments of offering expenses of $233,000 as of December 31, 2018, our pro forma as adjusted net tangible book value as of December 31, 2018 would have been $95.6 million, or $3.16 per share. This amount represents an immediate increase in pro forma as adjusted net tangible book value of $3.75 per share to our existing stockholders and an immediate dilution of $16.84 per share to investors purchasing shares in this offering. We determine dilution by subtracting the pro forma as adjusted net tangible book value per share after this offering from the amount of cash that a new investor paid for a share of common stock.

The following table illustrates this dilution:

| | | | | |
|---|---|---|---|---|
| Initial public offering price per share | | | $ | 20.00 |
| Historical net tangible book value per share as of December 31, 2018 | $ | (119.35) | | |
| Pro forma increase in net tangible book value per share | $ | 118.76 | | |
| Pro forma net tangible book value per share as of December 31, 2018 | $ | (0.59) | | |
| Increase in pro forma net tangible book value per share attributable to new investors in this offering | $ | 3.75 | | |
| Pro forma as adjusted net tangible book value per share after this offering | | | $ | 3.16 |
| Dilution per share to new investors in this offering | | | $ | 16.84 |

The following table summarizes, as of December 31, 2018, on a pro forma as-adjusted basis as described above, the difference between existing stockholders and new investors with respect to the number of shares of common stock purchased from us, the total consideration paid to us, and the average price per share paid, before deducting underwriting discounts and commissions and estimated offering expenses:

| | Shares Purchased | | Total Consideration | | Average Price Per Share |
|---|---|---|---|---|---|
| | Number | Percent | Amount | Percent | |
| Existing stockholders | 24,228,959 | 80% | $ 122,379,516 | 50% | $ 5.05 |
| New investors | 6,000,000 | 20% | 120,000,000 | 50% | $ 20.00 |
| Total | 30,228,959 | 100% | $ 242,379,516 | 100% | |

Except as otherwise indicated, the above discussion and tables assume no exercise of the underwriters' option to purchase additional shares of common stock from the selling stockholders. If the underwriters exercise their option to purchase additional shares in full, our existing stockholders would own 77.2% and our new investors would own 22.8% of the total number of shares of common stock outstanding upon the completion of this offering.

The number of shares of common stock that will be outstanding after this offering is based on 24,228,959 shares of common stock outstanding, assuming the conversion of all of our outstanding shares of convertible preferred stock and the automatic net exercise of outstanding warrants to purchase shares of convertible preferred stock and common stock as of December 31, 2018, in each case into common stock upon completion of this offering, at the initial public offering price of $20.00 per share, and excludes:

- 4,364,377 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock outstanding as of December 31, 2018, with a weighted-average exercise price of $3.79 per share;
- 32,950 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock granted after December 31, 2018, with an exercise price of $11.29 per share; and
- 2,775,939 shares of common stock reserved for future grants under our stock-based compensation plans, consisting of:
    - 24,939 shares of common stock reserved for future grants under our 2007 Stock Plan, which shares will be added to the shares to be reserved under our 2019 Equity Incentive Plan;
    - 2,317,000 shares of common stock reserved for future grants under our 2019 Equity Incentive Plan, including 654,792 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock granted to certain of our executive officers, directors and new employees pursuant to our 2019 Equity Incentive Plan, with a grant date of April 3, 2019, and with an exercise price equal to $20.00 per share; and
    - 434,000 shares of common stock reserved for future issuance under our 2019 Employee Stock Purchase Plan.

To the extent that any outstanding options to purchase shares of our common stock are exercised or new awards are granted under our equity compensation plans, there will be further dilution to investors participating in this offering.

# SELECTED CONSOLIDATED FINANCIAL DATA

We derived the selected consolidated statements of operations data for the years ended December 31, 2017 and December 31, 2018 and the consolidated balance sheet data as of December 31, 2017 and December 31, 2018 from our audited consolidated financial statements appearing elsewhere in this prospectus. You should read this data together with our consolidated financial statements and related notes thereto included elsewhere in this prospectus and the information under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations." The selected consolidated financial data included in this section are not intended to replace the consolidated financial statements and related notes thereto included elsewhere in this prospectus and are qualified in their entirety by the consolidated financial statements and related notes thereto included elsewhere in this prospectus. Our historical results are not necessarily indicative of our future results.

## Consolidated Statements of Operations Data:

| | Years Ended December 31, | |
|---|---|---|
| *(in thousands, except share and per share data)* | **2017** | **2018** |
| Revenue | $ 14,258 | $ 34,557 |
| Cost of goods sold | 5,129 | 10,874 |
| Gross profit | 9,129 | 23,683 |
| Operating expenses: | | |
| Research and development | 7,242 | 10,258 |
| Selling, general and administrative | 20,261 | 34,820 |
| Total operating expenses | 27,503 | 45,078 |
| Loss from operations | (18,374) | (21,395) |
| Interest income (expense), net | (3,909) | (4,172) |
| Other income (expense), net | 2,927 | (12,063) |
| Net loss | (19,356) | (37,630) |
| Net loss attributable to non-controlling interest | — | 1 |
| Net loss attributable to Silk Road Medical, Inc. common stockholders | $ (19,356) | $ (37,629) |
| Net loss per share attributable to Silk Road Medical, Inc. common stockholders, basic and diluted | $ (44.58) | $ (39.16) |
| Weighted average common shares used to compute net loss per share attributable to Silk Road Medical, Inc. common stockholders, basic and diluted | 434,158 | 960,882 |
| Pro forma net loss per share attributable to Silk Road Medical, Inc. common stockholders, basic and diluted [(1)] | | $ (1.07) |
| Pro forma weighted average common shares used to compute net loss per share attributable to Silk Road Medical, Inc. common stockholders, basic and diluted [(1)] | | 24,050,299 |

(1) See Note 2 to our consolidated financial statements for further details on the calculation of our historical and pro forma net loss per share, basic and diluted, and the weighted-average number of shares used in the per share amounts.

## Consolidated Balance Sheet Data:

| *(in thousands)* | As of December 31, 2017 | 2018 |
|---|---|---|
| Cash and cash equivalents | $ 33,331 | $ 24,990 |
| Working capital | 37,418 | 27,824 |
| Total assets | 43,086 | 40,881 |
| Long-term debt | 27,589 | 44,201 |
| Convertible preferred stock warrant liability | 4,185 | 16,091 |
| Convertible preferred stock | 105,235 | 105,235 |
| Accumulated deficit | (101,556) | (139,111) |
| Total stockholders' deficit | (98,578) | (134,553) |

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with the section entitled "Selected consolidated financial data" and our consolidated financial statements and related notes thereto included elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions, that are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this prospectus entitled "Risk Factors."*

## Overview

We are a medical device company focused on reducing the risk of stroke and its devastating impact. We believe a key to stroke prevention is minimally-invasive and technologically advanced intervention to safely and effectively treat carotid artery disease, one of the leading causes of stroke. We have pioneered a new approach for the treatment of carotid artery disease called transcarotid artery revascularization, or TCAR, which we seek to establish as the standard of care. We manufacture and sell in the United States our portfolio of TCAR products, which are designed to provide direct access to the carotid artery, effective reduction in stroke risk throughout the procedure, and long-term restraint of carotid plaque.

We began commercializing our products in the United States in late 2015. Our products are currently the only devices cleared and approved by the FDA specifically for transcarotid use. While our current commercial focus is on the U.S. market, our products have obtained CE Mark approval, allowing us to commercialize in Europe in the future. We also intend to pursue regulatory clearances in China, Japan, and other select international markets. TCAR is reimbursed based on established current procedural technology, or CPT, codes and International Classification of Diseases, or ICD-10, codes related to carotid stenting that track to Medicare Severity Diagnosis Related Group, or MS-DRG, classifications.

We designed our commercial strategy and built our direct sales force with a particular focus on vascular surgery practices. Vascular surgeons are skilled in endovascular procedures, and our sales and marketing efforts are focused on driving adoption and supporting their practice development by offering them an innovative, safe, effective and minimally-invasive alternative for treating carotid artery disease. We also market to other specialists with experience in CEA or CAS with the appropriate skill set for TCAR, including neurosurgeons, cardiothoracic surgeons and non-surgical interventionalists in radiology, neuroradiology and cardiology. We also work on developing strong relationships with physicians and hospitals that we have identified as key opinion leaders. We consider the hospitals and medical centers where the procedure is performed to be our customers, as they typically are responsible for purchasing our products. Our direct sales organization consists of 27 sales representatives and 41 clinical support specialists.

We manufacture and distribute the ENROUTE NPS at our facility in Sunnyvale, California, using components and sub-assemblies manufactured both in-house and by third party manufacturers and suppliers. We purchase our other products from third-party contract manufacturers, including our ENROUTE stent. Many of these third-party manufacturers and outside vendors are currently single-source suppliers. We expect that our existing manufacturing facility will be sufficient to meet our anticipated growth through at least the next four years.

To date, our primary sources of capital have been private placements of convertible preferred stock, debt financing arrangements and revenue from sales of our products. Since inception, we have raised a

total of $105.2 million in net proceeds from private placements of convertible preferred stock. As of December 31, 2018, we had cash and cash equivalents of $25.0 million, long-term debt of $44.2 million and an accumulated deficit of $139.1 million. During the year ended December 31, 2018, we generated revenue of $34.6 million and our net loss was $37.6 million.

***Key Business Metric - Number of U.S. TCAR procedures***

We regularly review a number of operating and financial metrics, including the number of procedures performed in the United States, to evaluate our business, measure our performance, identify trends affecting our business, formulate our business plan and make strategic decisions. The following table lists the number of procedures performed in each of the three month periods as indicated:

| | Three Months Ended | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | March 31, 2017 | June 30, 2017 | Sept. 30, 2017 | Dec. 31, 2017 | March 31, 2018 | June 30, 2018 | Sept. 30, 2018 | Dec. 31, 2018 |
| Number of procedures | 242 | 342 | 513 | 709 | 774 | 1,008 | 1,243 | 1,548 |

We define a procedure as any instance in which our ENROUTE NPS is used and for which we have a record that the procedure was performed. A procedure that is started and then aborted, or converted to a different procedure, after the ENTROUTE NPS is used would count as a procedure. The number of procedures is an indicator of our ability to drive adoption and generate revenue, and is helpful in tracking the progress of our business. We believe that it is representative of our current business; however, we anticipate this may be substituted for additional or different metrics as our business grows.

## Components of our Results of Operations

***Revenue***

We currently derive all of our revenue from the sale of our portfolio of TCAR products to hospitals and medical centers in the United States. Our customers typically purchase an initial stocking order of our products and then reorder as needed. Each of our products is purchased individually, and the majority of our revenue is derived from sales of the ENROUTE NPS and ENROUTE stent. No single customer accounted for 10% or more of our revenue during the years ended December 31, 2017 and 2018. We expect revenue to increase in absolute dollars as we expand our sales territories, new accounts and trained physician base and as existing physicians perform more TCAR procedures.

We expect our revenue to fluctuate from quarter-to-quarter due to a variety of factors, including seasonality. For example, in the first quarter, our results can be harmed by adverse weather and by resetting of annual patient healthcare insurance plan deductibles, both of which may cause patients to delay elective procedures. In the third quarter, the number of elective procedures nationwide is historically lower than other quarters throughout the year, which we believe is primarily attributable to the summer vacations of physicians and their patients, which results in fewer procedures.

***Cost of Goods Sold and Gross Margin***

We manufacture the ENROUTE NPS in California at our facility in Sunnyvale. We purchase our other products from third party manufacturers. Cost of goods sold consists primarily of costs related to materials, components and sub-assemblies, direct labor, manufacturing overhead, reserves for excess, obsolete and non-sellable inventories as well as distribution-related expenses. Overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. Cost of goods sold also includes depreciation expense for production equipment and certain direct costs such as those incurred for shipping our products and royalties related to the sale of our ENROUTE stent. We expense all inventory provisions as cost of goods

sold. We record adjustments to our inventory valuation for estimated excess, obsolete and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions. We expect cost of goods sold to increase in absolute dollars to the extent more of our products are sold.

We calculate gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily average selling prices, product sales mix, production and ordering volumes, manufacturing costs, product yields, headcount and cost-reduction strategies. We expect our gross margin to increase over the long-term as our production and ordering volumes increase and as we spread the fixed portion of our overhead costs over a larger number of units produced. We intend to use our design, engineering and manufacturing know-how and capabilities to further advance and improve the efficiency of our manufacturing processes, which we believe will reduce costs and have a positive impact on our gross margin. Our gross margin could fluctuate from quarter to quarter as we introduce new products, and as we adopt new manufacturing processes and technologies.

***Research and Development Expenses***

Research and development, or R&D, expenses consist primarily of engineering, product development, clinical studies to develop and support our products, regulatory expenses, medical affairs, and other costs associated with products and technologies that are in development. These expenses include employee compensation, including stock-based compensation, supplies, consulting, prototyping, testing, materials, travel expenses, depreciation and an allocation of facility overhead expenses. Additionally, R&D expenses include costs associated with our clinical studies, including clinical trial design, clinical trial site initiation and study costs, data management, related travel expenses and the cost of products used for clinical trials, internal and external costs associated with our regulatory compliance and quality assurance functions and overhead costs. We expect R&D expenses as a percentage of revenue to vary over time depending on the level and timing of our new product development efforts, as well as our clinical development, clinical trial and other related activities.

***Selling, General and Administrative Expenses***

Selling, general and administrative, or SG&A, expenses consist primarily of compensation for personnel, including stock-based compensation, related to selling and marketing functions, physician education programs, commercial operations and analytics, finance, information technology and human resource functions. Other SG&A expenses include sales commissions, training, travel expenses, promotional activities, marketing initiatives, market research and analysis, conferences and trade shows, professional services fees (including legal, audit and tax fees), insurance costs, general corporate expenses and allocated facilities-related expenses. We expect SG&A expenses to continue to increase in absolute dollars as we expand our infrastructure to both drive and support the anticipated growth in revenue and due to additional legal, accounting, insurance and other expenses associated with being a public company.

***Interest Income (Expense), net***

Interest income (expense), net consists primarily of interest incurred on our outstanding indebtedness and non-cash interest related to the amortization of debt discount and issuance costs associated with our term loan agreement. We may, at our election, pay the interest through a combination and the incurrence of additional indebtedness as payment-in-kind, or PIK.

***Other Income (Expense), net***

Other income (expense), net primarily consists of gains and losses resulting from the remeasurement of the fair value of our convertible preferred stock warrant liability at each balance sheet date. We will continue to record adjustments to the estimated fair value of the convertible preferred stock warrants until

they are exercised, which we expect to occur in connection with this offering. At that time, the final fair value of the warrant liability will be reclassified to stockholders' deficit and we will no longer record any related periodic fair value adjustments.

## Results of Operations:

| | Years Ended December 31, | |
|---|---|---|
| *(in thousands)* | **2017** | **2018** |
| Revenue | $ 14,258 | $ 34,557 |
| Costs of goods sold | 5,129 | 10,874 |
| Gross profit | 9,129 | 23,683 |
| Operating expenses: | | |
| Research and development | 7,242 | 10,258 |
| Selling, general and administrative | 20,261 | 34,820 |
| Total operating expenses | 27,503 | 45,078 |
| Loss from operations | (18,374) | (21,395) |
| Interest income (expense), net | (3,909) | (4,172) |
| Other income (expense), net | 2,927 | (12,063) |
| Net loss and comprehensive loss | $ (19,356) | $ (37,630) |

***Comparison of Years Ended December 31, 2017 and 2018***

*Revenue.* Revenue increased $20.3 million, or 142%, to $34.6 million during the year ended December 31, 2018, compared to $14.3 million during the year ended December 31, 2017. The increase in revenue was attributable to an increase in the number of products sold as we expanded our sales territories, increased the number of new accounts, trained more physicians in TCAR and as physicians performed more TCAR procedures.

*Cost of Goods Sold and Gross Margin.* Cost of goods sold increased $5.8 million, or 112%, to $10.9 million during the year ended December 31, 2018, compared to $5.1 million during the year ended December 31, 2017. This increase was attributable to the increase in the number of products sold and additional manufacturing overhead costs as we invested significantly in our operational infrastructure to support anticipated future growth. Gross margin for the year ended December 31, 2018 increased to 69%, compared to 64% in the year ended December 31, 2017. Gross margin increased as our production and ordering volumes increased and we were able to spread the fixed portion of our overhead costs over a larger number of units produced.

*Research and Development Expenses.* R&D expenses increased $3.1 million, or 42%, to $10.3 million during the year ended December 31, 2018, compared to $7.2 million during the year ended December 31, 2017. The increase in R&D expenses was primarily attributable to an increase of $2.2 million in personnel-related expenses including stock-based compensation, an increase of $0.3 million in outside services, an increase of $0.3 million in travel related costs, and an increase of $0.2 million relating to the allocation of facilities expense.

*Selling, General and Administrative Expenses.* SG&A expenses increased $14.5 million, or 71%, to $34.8 million during the year ended December 31, 2018, compared to $20.3 million during the year ended December 31, 2017. The increase in SG&A costs was due to the continued commercialization of our products and is primarily attributable to an increase of $9.8 million in personnel-related expenses, an increase of $1.2 million relating to the allocation of facilities and related expenses, an increase of $1.0 million in physician training and travel related costs, an increase of $1.0 million in travel expenses, an

increase of $0.8 million in consulting, legal and professional fees, an increase of $0.6 million in marketing, tradeshow and promotional costs and an increase of $0.3 million in software related expense. Personnel-related expenses included stock-based compensation expense of $0.4 million and $0.6 million for the years ended December 31, 2017 and 2018, respectively.

*Interest Income (Expense), Net.* Interest income (expense), net increased $0.3 million, or 7%, to an expense of $4.2 million during the year ended December 31, 2018, compared to an expense of $3.9 million during the year ended December 31, 2017. This increased expense was attributable to the additional interest expense associated with the $5.0 million of additional borrowings in April 2017 and $15.0 million of additional borrowings in September 2018 under our term loan agreement. As of December 31, 2017 and 2018, the aggregate balance of outstanding principal balance (including interest paid-in-kind) under the term loan agreement was $27.6 million and $44.2 million, respectively.

*Other Income (Expense), Net.* Other income (expense), net decreased to an expense of $12.1 million during the year ended December 31, 2018, compared to income of $2.9 million during the year ended December 31, 2017. The decrease was primarily attributed to the remeasurement of our convertible preferred stock warrants and recognition of the change in fair value.

***Selected Quarterly Financial Information***

The following table represents certain unaudited quarterly information for the four quarters ended December 31, 2018. The unaudited quarterly information set forth below has been prepared on a basis consistent with our audited annual consolidated financial statements included elsewhere in this prospectus and include, in our opinion, all normal recurring adjustments necessary for the fair presentation of the results of operations for the periods presented. Our historical quarterly results are not necessarily indicative of the results that may be expected in the future. The following quarterly financial information should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere in this prospectus.

| | For the Three Months Ended | | | |
|---|---|---|---|---|
| *(in thousands)* | **March 31, 2018** | **June 30, 2018** | **September 30, 2018** | **December 31, 2018** |
| Revenue | $ 5,706 | $ 7,767 | $ 9,614 | $ 11,470 |
| Costs of goods sold | 1,934 | 2,391 | 2,882 | 3,667 |
| Gross profit | 3,772 | 5,376 | 6,732 | 7,803 |
| Operating expenses: | | | | |
| Research and development | 2,100 | 2,326 | 2,442 | 3,390 |
| Selling, general and administrative | 6,319 | 7,816 | 8,973 | 11,712 |
| Total operating expenses | 8,419 | 10,142 | 11,415 | 15,102 |
| Loss from operations | (4,647) | (4,766) | (4,683) | (7,299) |
| Interest income (expense), net | (976) | (987) | (1,037) | (1,172) |
| Other income (expense), net | 215 | (1,898) | (3,233) | (7,147) |
| Net loss and comprehensive loss | $ (5,408) | $ (7,651) | $ (8,953) | $ (15,618) |

## Liquidity and Capital Resources

To date, our primary sources of capital have been private placements of convertible preferred stock, debt financing agreements and revenue from the sale of our products. As of December 31, 2018, we had cash and cash equivalents of $25.0 million, an accumulated deficit of $139.1 million and $44.2 million outstanding under our term loan agreement. Our recurring losses from operations and negative cash

flows raise doubt about our ability to continue as a going concern. As a result, we have concluded that there is substantial doubt about our ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. See Note 1 to our consolidated financial statements included elsewhere in this prospectus for additional information. Similarly, our independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statements as of and for the year ended December 31, 2018, describing the existence of substantial doubt about our ability to continue as a going concern. We believe that the net proceeds from this offering together with our existing cash and cash equivalents, expected revenue and additional borrowings available under the term loan agreement, will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months. If these sources are insufficient to satisfy our liquidity requirements, we may seek to raise additional funds through future equity or debt financings. If we raise additional funds by issuing equity securities, our stockholders would experience dilution. Additional debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. There can be no assurance that our efforts to procure additional financing will be successful or that, if they are successful, the terms and conditions of such financing will be favorable to us or our stockholders. If we are unable to raise additional financing when needed, we may be required to delay, reduce, or terminate the development, commercialization and marketing of our products and scale back our business and operations.

## Cash Flows

The following table summarizes our cash flows for each of the years ended December 31:

| | Years Ended December 31, | |
|---|---|---|
| *(in thousands)* | **2017** | **2018** |
| Net cash (used in) provided by: | | |
| Operating activities | $ (25,252) | $ (21,695) |
| Investing activities | (443) | (2,270) |
| Financing activities | 47,156 | 15,424 |
| Net increase (decrease) in cash, cash equivalents and restricted cash | $ 21,461 | $ (8,541) |

***Net Cash Used in Operating Activities***

Net cash used in operating activities for the year ended December 31, 2018 was $21.7 million, consisting primarily of a net loss of $37.6 million and an increase in net operating assets of $1.0 million, partially offset by non-cash charges of $16.9 million. The increase in net operating assets was primarily due to an increase in accounts receivable, inventories and prepaid expenses and other current assets to support the growth of our operations, partially offset by increases in accrued and other liabilities, due to timing of payments and growth of our operations. The non-cash charges primarily consisted of depreciation, stock-based compensation, provision for accounts receivable allowances, non-cash interest expense and other charges related to our term loan agreement, and increase in the fair value of the convertible preferred stock warrants.

Net cash used in operating activities for the year ended December 31, 2017 was $25.3 million, consisting primarily of a net loss of $19.4 million and an increase in net operating assets of $5.9 million. The increase in net operating assets was primarily due to an increase in accounts receivable and inventories to support the growth of our operations, partially offset by increases in accounts payable and accrued liabilities, due to timing of payments and growth of our operations. We also had non-cash charges, which consisted of depreciation, stock-based compensation, provision for accounts receivable allowances, non-cash interest expense and other charges related to our term loan agreement, offset by the decrease in fair value of the convertible preferred stock warrants.

***Net Cash Used in Investing Activities***

Net cash used in investing activities in the year ended December 31, 2018 was $2.3 million primarily consisting of purchases of property and equipment.

Net cash used in investing activities in the year ended December 31, 2017 was $0.4 million consisting of purchases of property and equipment.

***Net Cash Provided by Financing Activities***

Net cash provided by financing activities in the year ended December 31, 2018 of $15.4 million primarily relates to proceeds of $15.0 million from additional borrowings under the term loan agreement, and $0.7 million proceeds from the exercise of stock options, partially offset by cash paid for deferred initial public offering costs of $0.2 million.

Net cash provided by financing activities in the year ended December 31, 2017 of $47.2 million primarily relates to net proceeds of $41.8 million from the issuance of our Series C convertible preferred stock, proceeds of $5.0 million from additional borrowings under the term loan agreement, and $0.3 million proceeds from the exercise of stock options.

## Term Loan Agreement

In October 2015, we entered into the term loan agreement and related security agreement with CRG, providing for a term loan facility of up to $30.0 million, available in tranches on the terms and conditions set forth in the term loan agreement. In September 2018, we entered into a fifth amendment to the term loan agreement, or Fifth Amendment, to increase the aggregate term loan commitments from up to $30.0 million to up to $55.0 million, to extend the commitment period from March 29, 2017 to June 30, 2019, to extend the maturity date from September 30, 2021 to December 31, 2022, and to amend certain other terms.

As of December 31, 2018, the aggregate outstanding principal balance (including interest paid-in-kind, or PIK) under the term loan agreement was $44.2 million.

Prior to the Fifth Amendment, the term loans bore interest at a rate of 13.0% per annum, which interest rate was reduced to 10.75% on and after the effective date of the Fifth Amendment, and which interest rate would be further reduced to 10.00% on and after the consummation of a qualified initial public offering. We may, at our election, pay the interest through a combination of cash and PIK. The interest is payable in cash and PIK as follows: prior to the Fifth Amendment, 8.50% per annum in cash and 4.50% PIK; on or after the Fifth Amendment, 8.0% per annum in cash and 2.75% PIK; and on and after the consummation of a qualified initial public offering, 8.0% per annum in cash and 2.0% PIK. Interest is due and payable quarterly in arrears. The outstanding principal amount under the term loan agreement, together with all accrued and unpaid interest, is due and payable on December 31, 2022. We may prepay the term loan agreement, in whole or in part, at any time. During 2018, we incurred $4.3 million in interest expense in connection with the term loan agreement. During 2018, we made cash interest payments of $2.7 million and issued $1.2 million in PIK interest for the year ended December 31, 2018.

Our obligations under the term loan agreement are guaranteed by our existing and future subsidiaries, subject to exceptions for certain foreign subsidiaries. Our obligations under the term loan agreement are secured by substantially all of our assets, including our material intellectual property, and the assets of our guarantor subsidiaries, subject to certain exceptions. There are currently no guarantor subsidiaries. Additionally, we and our subsidiaries are subject to customary affirmative and negative covenants, including covenants that limit or restrict the ability of us and our subsidiaries to, among other things, incur indebtedness, grant liens, merge or consolidate, make investments, dispose of assets, make

acquisitions, pay dividends or make distributions, repurchase stock and enter into certain transactions with affiliates, in each case subject to certain exceptions. We are also required to maintain minimum liquidity that exceeds the greater of $3.0 million or the minimum cash balance required under any permitted accounts receivable credit facility. In addition, we must achieve minimum annual revenue of $30.0 million in 2019 and $40.0 million in 2020. If we fail to satisfy the minimum annual revenue covenant in any measurement period, we can cure the resulting default by raising the revenue shortfall in additional equity or in subordinated debt within 90 days of such calendar year in which the shortfall occurred. As of the date of this prospectus, we were in compliance with all covenants under the term loan agreement.

The term loan agreement is subject to customary events of default that include, among other things, non-payment defaults, inaccuracy of representations and warranties, covenant defaults, cross-defaults to material indebtedness and material agreements, bankruptcy and insolvency defaults, material judgment defaults, ERISA defaults, a change of control default and a material adverse change default. The occurrence of an event of default could result in the acceleration of the obligations under the term loan agreement. Under certain circumstances, a default interest rate will apply on all obligations during the existence of an event of default at a per annum rate equal to 4.0% above the applicable interest rate. On November 14, 2018, we entered into a sixth amendment to the term loan agreement to amend a covenant regarding the timeline for production of audited financial statements.

## Cordis License Agreement

In December 2010, we entered into a license agreement, or the Cordis License Agreement, with Cordis Corporation, or Cordis, which is now a subsidiary of Cardinal Health. Pursuant to the Cordis License Agreement, Cordis has granted us a worldwide, non-exclusive, royalty-bearing license to certain of its intellectual property related to the PRECISE® carotid stent, or the Licensed IP, for transcervical treatment of carotid artery disease with an intravascular stent for certain applications for accessing blood vessels through the neck and cervical area. Cordis may not license the Licensed IP in our licensed field of use to any other third party during the term of the Cordis License Agreement.

We have paid Cordis a one-time license execution fee and are obligated to pay royalties to Cordis on a calendar quarter basis during the term of the Cordis License Agreement, calculated based on net sales of the licensed products we sell during the preceding quarterly period. The license granted under Cordis License Agreement shall remain in full force and effect on a country by country basis until the last to expire of the Licensed IP in such country.

The Cordis License Agreement requires us to work exclusively with either Cordis or Confluent Medical Technologies, Inc. (f/k/a Nitinol Devices and Components, Inc.), or Confluent, for the development, manufacture and supply of the licensed products. If either Cordis or Confluent cannot continue to manufacture or supply the licensed products, we can seek a third party manufacturer with the prior written consent of Cordis.

We have the right to assign or transfer the Cordis License Agreement to an entity that succeeds all or substantially all of our equity or assets. The Cordis License Agreement may be terminated by either party in the event of uncured material breach by the other party that remains uncured for 60 days (or 30 days for payment related breaches), or bankruptcy of the other party.

## Cordis Supply Agreement

In October 2011, we entered into a supply agreement, or Cordis Supply Agreement, with Cordis and have since entered into four amendments in March and July 2012, April 2013 and April 2018. Pursuant to the Cordis Supply Agreement, Cordis has assisted in the development of a transcarotid stent delivery system according to our specifications with a PRECISE® carotid stent implant, or ENROUTE stent, has supplied the ENROUTE stent through preclinical and clinical trials, and continues to supply the

ENROUTE stent for our commercial sale. The Cordis Supply Agreement will continue in full force and effect until the earlier to occur of (i) termination of the Cordis License Agreement; (ii) our election if and when Cordis approves another manufacturer; (iii) mutual written termination; or (iv) termination pursuant to the terms therein. The Cordis Supply Agreement may be terminated by either party in the event of uncured material breach by the other party that remains uncured for 30 days, or bankruptcy of the other party.

We are obligated under the Cordis Supply Agreement to purchase a minimum volume of the ENROUTE stent annually. This obligation is binding until the natural expiration of the Cordis License Agreement, due to expiration of the last-to-expire of the Licensed IP, if the Cordis License Agreement remains in effect through such natural expiration.

Cordis has the exclusive right to manufacture and supply the ENROUTE stent during the term of the Cordis Supply Agreement. However, if Cordis is not able to supply the ENROUTE stent, upon our election, Cordis shall permit Confluent or a third party manufacturer to provide supply of the ENROUTE stent, provided that Cordis retains the right to manufacture and supply the ENROUTE stent to us to the extent it is able to do so. Notwithstanding the foregoing, we, without Cordis' consent, may work directly with Confluent for the development and supply of next-generation products that materially expand or change the specification of the ENROUTE stent.

## Lease Agreements

We currently lease our headquarters in Sunnyvale, California pursuant to a lease agreement which terminates in October 2024. We have an additional option to extend the lease term for a period of five years. The option must be exercised no more than 12 months and no less than nine months prior to the expiration of the applicable term. The facility lease is for approximately 31,000 square feet.

## Off-Balance Sheet Arrangements

We currently have no off-balance sheet arrangements, such as structured finance, special purpose entities, or variable interest entities.

## Contractual Obligations and Commitments

Our principal obligations consist of the operating lease for our facility, our term loan agreement and non-cancellable inventory purchase commitments. The following table sets out, as of December 31, 2018, our contractual obligations due by period:

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| *(in thousands)* | Less Than 1 Year | 1-3 Years | 3-5 Years | More Than 5 Years | Total |
| Operating lease obligations | $ 1,002 | $ 2,033 | $ 2,109 | $ 855 | $ 5,999 |
| Term loan agreement with CRG | 3,566 | 7,448 | 52,510 | — | 63,524 |
| Non-cancellable purchase commitments | 4,648 | — | — | — | 4,648 |
| | $ 9,216 | $ 9,481 | $ 54,619 | $ 855 | $ 74,171 |

The non-cancellable purchase commitments primarily consist of ENROUTE stents and other inventory components.

Our contractual obligations have not otherwise significantly changed from December 31, 2018.

## Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

While our significant accounting policies are more fully described in Note 2 of our consolidated financial statements included in this prospectus, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to our financial condition and results of operations and require our most difficult, subjective and complex judgments.

***Revenue Recognition***

We adopted Accounting Standards Codification, or ASC, Topic 606, "Revenue from Contracts with Customers," using the modified retrospective method applied to contracts which were not completed as of that date effective January 1, 2018. Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, we perform the following five steps:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the entity satisfies a performance obligation.

Our revenue is generated from the sale of our products to hospitals and medical centers in the United States through direct sales representatives. Revenue is recognized when obligations under the terms of a contract with customers are satisfied, which occurs with the transfer of control of our products to customers, either upon shipment of the product or delivery of the product to the customer under our standard terms and conditions. Revenue is measured as the amount of consideration we expect to receive in exchange for transferring the goods.

For sales where the sales representative hand delivers product directly to the hospital or medical center from the sales representative's trunk stock inventory, we recognize revenue upon delivery, which represents the point in time when control transfers to the customer. For sales which are sent directly to hospitals and medical centers, the transfer of control occurs at the time of shipment or delivery of the product. There are no further performance obligations by us or the sales representative to the customer after delivery under either method of sale.

We accept product returns at our discretion or if the product is defective as manufactured. We establish estimated provisions for returns based on historical experience. We have elected to expense shipping and handling costs as incurred and include them within cost of goods sold. In those cases

where we invoice shipping and handling costs to customers, we will classify the amounts billed as a component of revenue.

As noted, revenue for the year ended December 31, 2018 is presented under ASC 606, while prior period revenue amounts are not adjusted and continue to be reported in accordance with our historic accounting under ASC 605, "Revenue Recognition." Under ASC 605, we recognized revenue when all of the following criteria were met:

- Persuasive evidence of an arrangement exists;
- The sales price is fixed or determinable;
- Collection of the relevant receivable is reasonably assured at the time of sale; and
- Delivery has occurred or services have been rendered.

We recognized revenue when title to the goods and risk of loss transferred to the customer, which was upon shipment of the product under our standard terms and conditions. We estimated reductions in revenue for potential returns of products by customers. In making such estimates, we analyzed historical returns, current economic trends and changes in customer demand and acceptance of our products. We expensed shipping and handling costs as incurred and included them in the cost of goods sold. In those cases where we billed shipping and handling costs to customers, we would classify the amounts billed as a component of revenue.

***Inventories***

Inventories, which includes material, labor and overhead costs, are stated at cost, determined on a first-in, first-out basis, and not in excess of net realizable value. We periodically assess inventory quantities in consideration of actual loss experience, projected future demand, and remaining shelf life to determine whether provisions for impairment are required. Our policy is to write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements based on future demand and as compared to remaining shelf life. The written down value of the inventory becomes its new cost basis. The estimate of excess quantities is subjective and primarily dependent on our estimates of future demand for a particular product. If the estimate of future demand is inaccurate based on actual sales, we may increase the write down for excess inventory for that component and record a charge to inventory impairment in the accompanying consolidated statements of operations and comprehensive loss.

***Common Stock Valuation and Stock-Based Compensation***

We maintain an equity incentive plan to provide long-term incentive for employees, consultants and members of our board of directors. The plan allows for the issuance of non-statutory and incentive stock options to employees and non-statutory stock options to consultants and non-employee directors.

We recognize compensation costs related to stock options granted to employees based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option pricing model. The grant date fair value of stock-based awards is expensed on a straight-line basis over the period during which the employee is required to provide service in exchange for the award, which is typically the vesting period. We account for forfeitures as they occur.

We estimate the fair value of our stock-based awards using the Black-Scholes option-pricing model, which requires the input of highly subjective assumptions. Our assumptions are as follows:

*Fair Value of Common Stock.* As our common stock has never been publicly traded, the fair value of the shares of our common stock underlying the stock options has historically been determined by our board of directors with input from management, after considering independent third-party valuation reports. Because there had previously been no public market for our common stock, our board of directors determined the fair value of our common stock at the time of grant of the option by considering a number of objective and subjective factors, including valuations of comparable companies, sales of our convertible preferred stock, our operating and financial performance and the general and industry-specific economic outlook.

*Expected Term.* We do not believe we are able to rely on our historical exercise and post-vesting termination activity to provide accurate data for estimating the expected term for use in determining the fair value-based measurement of our options. Therefore, we have opted to use the "simplified method" for estimating the expected term of options, which is the average of the weighted average vesting period and contractual term of the option. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method. For awards with multiple vesting-tranches, the times from grant until the mid-points for each of the tranches may be averaged to provide an overall expected term.

*Expected Volatility.* As our common stock has never been publicly traded, the expected volatility is derived from the average historical volatilities of publicly traded companies within our industry that we consider to be comparable to our business over a period approximately equal to the expected term for employees' options and the remaining contractual life for nonemployees' options. In evaluating similarity, we considered factors such as stage of development, risk profile, enterprise value and position within the life sciences industry.

*Risk-free Interest Rate.* The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for zero-coupon U.S. Treasury notes with remaining terms similar to the expected term of the options.

*Dividend Rate.* We assumed the expected dividend to be zero as we have never paid dividends and have no current plans to do so.

We will continue to use judgment in evaluating the expected volatility and expected terms utilized for our stock-based compensation calculations on a prospective basis. As we continue to accumulate additional data, we may have refinements to our assumptions, which could materially impact our future stock-based compensation expense. For performance-based stock options, we assess the probability of performance conditions being achieved in each reporting period. The amount of stock-based compensation expense recognized in any one period related to performance-based stock options can vary based on the achievement or anticipated achievement of the performance conditions.

We amortize all stock-based compensation on a straight-line basis over the requisite service period of the awards, which is generally the same as the vesting period of the awards.

We expect to continue to grant stock options and other equity-based awards in the future, and to the extent that we do, our stock-based compensation expense recognized in future periods will likely increase.

***Estimated fair value of convertible preferred stock warrants***

We have issued freestanding warrants to purchase shares of convertible preferred stock in connection with the issuance of our convertible preferred stock. We account for these warrants as a liability in our financial statements because the underlying instrument into which the warrants are exercisable contains deemed liquidation provisions that are outside our control.

The warrants are recorded at fair value using an option pricing model based on an allocation of our aggregate value to the outstanding equity instruments, applying a discount to the warrant value for lack of marketability. The warrants are subject to remeasurement at each balance sheet date with any changes in fair value being recognized as a component of other income (expense), net in the statements of operations. We will continue to adjust the liability for changes in fair value until the earlier of (i) exercise or expiration of the warrants, or (ii) the completion of this offering or a change of control, at which time outstanding convertible preferred stock warrants will be exercised for shares of common stock and the related final fair value of the warrant liability will be reclassified to stockholders' deficit.

## Quantitative and Qualitative Disclosures About Market Risk

***Interest Rate Risk***

The risk associated with fluctuating interest rates is primarily limited to our cash equivalents, which are carried at quoted market prices. Due to the short-term maturities and low risk profile of our cash equivalents, an immediate 100 basis point change in interest rates would not have a material effect on the fair value of our cash equivalents. We do not currently use or plan to use financial derivatives in our investment portfolio.

***Credit Risk***

As of December 31, 2018, our cash and cash equivalents were maintained with two financial institutions in the United States, and our current deposits are likely in excess of insured limits. We have reviewed the financial statements of these institutions and believe each to have sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us. Our cash equivalents are invested in highly rated money market funds.

Our accounts receivable primarily relate to revenue from the sale of our products to hospitals and medical centers in the United States. No customer represented 10% or more of our accounts receivable as of December 31, 2018.

***Foreign Currency Risk***

Our business is primarily conducted in U.S. dollars. Any transactions that may be conducted in foreign currencies are not expected to have a material effect on our results of operations, financial position or cash flows.

## JOBS Act Accounting Election

As an emerging growth company under the Jumpstart Our Business Startups Act of 2012, we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We have irrevocably elected not to avail ourselves of the exemption from new or revised accounting standards and, therefore, are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

## Recently Issued Accounting Pronouncements

See Note 3 to our consolidated financial statements included elsewhere in this prospectus for new accounting pronouncements not yet adopted as of the date of this prospectus.

## Related Parties

For a description of our related party transactions, see "Certain Relationships and Related Party Transactions."

## Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed by, or under the supervision of, that company's principal executive and principal financial officers, or persons performing similar functions, and influenced by that company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate.

In connection with our preparation for this offering, we concluded that there were two material weaknesses in our internal control over financial reporting for the year ended December 31, 2017. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The first material weakness identified was that we did not maintain a sufficient complement of resources with an appropriate level of accounting knowledge, experience and training commensurate with our structure and financial reporting requirements. The second material weakness was that we did not appropriately design and implement controls over the review and approval of manual journal entries and the related supporting journal entry calculations.

During 2018 and in preparation for this offering, we initiated various remediation efforts, including increasing the depth and experience within our accounting and finance organization, as well as designing and implementing improved processes and internal controls. We have added and are continuing to add appropriate full-time resources to our finance team with public company and technical accounting experience to facilitate accurate and timely accounting closes, and to accurately prepare and review financial statements and related footnote disclosures. As a result of the additional resources added to the finance function, we are allowing for separate preparation and review of the reconciliations and other account analyses. In addition, these additional finance resources are allowing us to develop a more structured close process, including enhancing our existing policies and procedures, to improve the completeness, timeliness and accuracy of our financial reporting and disclosures including, but not limited to, those regarding proper financial statement classification and assessing more judgmental areas of accounting. The actions that have been taken are subject to continued review, supported by confirmation and testing by management, as well as audit committee oversight. As such remediation efforts are still ongoing, we have concluded that the material weakness has not been remediated. While we have implemented a plan to remediate these material weaknesses, we cannot provide any assurance that it will be successful, which could impair our ability to accurately and timely report our financial position, results of operations or cash flows.

# BUSINESS

## Overview

We are a medical device company focused on reducing the risk of stroke and its devastating impact. We believe a key to stroke prevention is minimally-invasive and technologically advanced intervention to safely and effectively treat carotid artery disease, one of the leading causes of stroke. We have pioneered a new approach for the treatment of carotid artery disease called transcarotid artery revascularization, or TCAR, which we seek to establish as the standard of care.

TCAR relies on two novel concepts - minimally-invasive direct carotid access in the neck and high-rate blood flow reversal during the procedure to protect the brain - and combines the benefits of innovative endovascular techniques with fundamental surgical principles. TCAR using our portfolio of products has been clinically demonstrated to reduce the upfront morbidity and mortality profile of current treatment alternatives while providing a reduction in long-term stroke risk. We are the first and only company to obtain FDA approvals, secure specific Medicare reimbursement coverage, and commercialize products engineered and indicated for use in TCAR. As of December 31, 2018, more than 7,750 TCAR procedures have been performed globally, including more than 4,600 in 2018.

Carotid artery disease is the progressive buildup of plaque causing narrowing of the arteries in the front of the neck, which supply blood flow to the brain. Plaque can embolize, or break away from the arterial wall, and travel toward the brain and interrupt critical blood supply, leading to an ischemic stroke. Carotid artery disease is one of the leading causes of stroke, and stroke is one of the most catastrophic, debilitating, and costly conditions worldwide. We believe the best way to mitigate the mortality, morbidity and cost burden of stroke is to prevent strokes in the first place. Clinical evidence has demonstrated that with proper diagnosis and treatment, stroke due to carotid artery disease is mostly preventable. We believe there were approximately 4.3 million people with carotid artery disease in the United States in 2018, with an estimated 427,000 new diagnoses in 2018, and existing treatment options have substantial safety and effectiveness limitations.

The goal of treating carotid artery disease is to prevent a future stroke. Unfortunately, one of the main complications of existing treatments for carotid artery disease is causing a stroke, along with other procedure-related adverse events. When intervention beyond medical management is warranted, the current standard of care for reduction in stroke risk is an invasive carotid revascularization procedure called carotid endarterectomy, or CEA. To perform a CEA, a physician makes a large incision in the neck, cuts the carotid artery open, and then removes the plaque from inside the vessel. CEA was first performed in 1953, and while generally effective at reducing stroke risk in the long term, large randomized clinical trials have demonstrated that CEA is associated with an upfront risk of adverse events from the procedure, including cranial nerve injury, heart attack, wound complications and even stroke and death. These risks are elevated in certain patient populations.

To address the invasiveness of CEA, transfemoral carotid artery stenting, or CAS, was developed in the 1990s. The CAS procedure uses minimally-invasive catheters traveling from a puncture site in the groin to place a stent in the carotid artery in the neck to restrain the plaque and prevent embolization that could cause a stroke. While both CEA and CAS have been clinically demonstrated to reduce long-term stroke risk, randomized clinical trials and other studies have shown that CAS, relative to CEA, often results in an almost two-fold increase in stroke within 30 days following treatment, which we believe is due to inadequate protection of the brain. We believe this represents an unacceptable trade-off relative to the current standard of care of CEA. As such, after almost 30 years of development, CAS has achieved limited adoption and narrow reimbursement coverage in the United States. CEA remains the standard of care and represented approximately 83% of the approximately 168,000 carotid revascularization procedures performed in the United States in 2018. Therefore, we believe solving for the morbidity and mortality of CEA is an unmet clinical need that continues to persist.

TCAR is a minimally-invasive solution that addresses the morbidity of CEA and the 30-day stroke risk of CAS while maintaining a reduction in long-term stroke risk beyond the first 30 days. TCAR starts with a small incision in the neck slightly above the collarbone, otherwise known as transcarotid access, through which our ENROUTE Transcarotid Stent System, or ENROUTE stent, is placed during a period of temporary high-rate blood flow reversal that is enabled by our ENROUTE Transcarotid Neuroprotection System, or ENROUTE NPS. Blood flow reversal directs embolic debris that could cause a stroke away from the brain, while the stent braces the plaque and prevents embolization to afford a reduction in long-term stoke risk. We believe that by meeting the standard of brain protection and reduction in 30-day and long-term stroke risk afforded by CEA, while providing benefits commensurate with an endovascular, minimally-invasive approach, TCAR will become the preferred alternative for carotid revascularization. Additionally, we believe that as our technology becomes more widely adopted, TCAR may become a compelling alternative for patients who are treated with medical management alone each year.

Based on the estimated 427,000 new carotid artery disease diagnoses that occurred in the United States in 2018, we believe a total annual U.S. market opportunity of approximately $2.6 billion exists for our portfolio of TCAR products. We are currently focused on penetrating and converting carotid revascularization procedures to TCAR. There were approximately 168,000 carotid revascularization procedures performed in 2018, which we estimate to represent a market conversion opportunity greater than $1.0 billion. Over 4,500 TCAR procedures were performed in 2018 in the United States using our products, representing approximately 1% of annual diagnoses of carotid artery disease in the United States.

The safety, effectiveness and clinical advantages of TCAR have been demonstrated in multiple clinical trials, post-market studies and registries that have evaluated outcomes in more than 3,500 patients in the United States and Europe to date. The results of our U.S. pivotal trial, ROADSTER, reflect the lowest reported 30-day stroke rate for any prospective, multicenter clinical trial of carotid stenting of which we are aware. Additionally, data on real-world outcomes of TCAR relative to CEA and CAS have continued to accrue through the ongoing TCAR Surveillance Project, which is an ongoing open-ended registry sponsored by the Society for Vascular Surgery through the Vascular Quality Initiative, or VQI. In a recent contemporaneous comparative analysis of this data, TCAR demonstrated comparable rates of in-hospital stroke and death relative to CEA despite treating a sicker, older patient population. TCAR patients had a ten-fold reduction in risk of cranial nerve injury, spent less time in the operating room and were less likely to have a hospital stay greater than one day. When compared to CAS, TCAR demonstrated significantly lower rates of in-hospital stroke and death.

We manufacture the ENROUTE NPS and distribute our portfolio of TCAR products from our facility in Sunnyvale, California. We market and sell our products in the United States through a direct sales organization consisting of 27 sales representatives and 41 clinical support specialists that are focused on driving adoption of TCAR among the approximately 2,750 physicians and 750 hospitals in the United States that we believe are responsible for over 80% of carotid revascularization procedures each year. While our current commercial focus is on the U.S. market, our ENROUTE NPS and ENROUTE stent have obtained CE Mark approval, allowing us to commercialize in Europe in the future. We are also pursuing regulatory clearances in China and Japan.

TCAR is reimbursed based on established current procedural technology, or CPT, codes and International Classification of Diseases, or ICD-10, codes related to carotid stenting that track to Medicare Severity Diagnosis Related Group, or MS-DRG classifications. In September 2016, the Centers for Medicare and Medicaid Services, or CMS, made coverage available for TCAR in symptomatic and asymptomatic patients at high risk for adverse events from CEA, or high surgical risk, treated at facilities participating in the Society for Vascular Surgery's TCAR Surveillance Project using FDA-cleared and approved transcarotid devices. Our ENROUTE NPS and stent are currently the only FDA-cleared and approved transcarotid devices. Carotid artery disease is most often a disease of the elderly and, as such, CMS is the primary payer for carotid revascularization procedures, and we estimate that the high surgical risk patient population represents approximately two-thirds of the treated patient population. We plan to

pursue expansion of FDA labeling for the ENROUTE stent, currently indicated for use in high surgical risk patients, and pursue CMS coverage for TCAR in the estimated one-third of treated patients who are deemed standard surgical risk.

We have experienced considerable growth since we began commercializing our products in the United States in late 2015. Our revenue increased from $14.3 million for the year ended December 31, 2017 to $34.6 million for the year ended December 31, 2018, representing growth of 142%, and our net losses were $19.4 million and $37.6 million for the years ended December 31, 2017 and December 31, 2018, respectively. Our accumulated deficit was $139.1 million as of December 31, 2018.

## Our Competitive Strengths

We believe the continued growth of our company will be driven by the following competitive strengths:

- **Paradigm-shifting transcarotid access and flow reversal technologies.** TCAR is an entirely new, minimally-invasive procedure in a disease state that has been defined by a 65-year-old standard of care. TCAR combines two innovative concepts: minimally-invasive direct carotid access in the neck, and high-rate blood flow reversal to protect the brain. Our technology combines the benefits of innovative endovascular techniques with fundamental surgical principles. Our goal is to leverage our disruptive technology and growing body of clinical evidence to establish TCAR with our products as the standard of care for the treatment of carotid artery disease.

- **Compelling body of clinical and economic evidence.** The benefits of TCAR are supported by data from over 3,500 patients enrolled across several multi-center clinical trials, post market studies and real-world registries that support favorable patient outcomes and value-based care. In November 2015, the Journal of Vascular Surgery reported that TCAR demonstrated the lowest 30-day stroke rate of any prospective, multicenter carotid stent trial. Data from the Society for Vascular Surgery's TCAR Surveillance Project show that TCAR compares favorably to CEA and CAS with a low 30-day stroke risk and low procedure-related adverse events. TCAR has demonstrated shorter procedure times, a shorter length of hospital stay and reduced adverse event rates compared to the standard of care, CEA. For hospitals seeking to improve quality metrics, drive throughput and increase profitability, we believe TCAR results in higher efficiency and increased cost savings. In addition, by reducing the overall burden of stroke, TCAR is beneficial to payers. We believe our growing body of clinical evidence and favorable value proposition will continue to support increased adoption of TCAR.

- **Established reimbursement linked to our unique regulatory label.** TCAR is reimbursed under established codes and payment levels. CMS coverage for TCAR in high surgical risk patients treated at facilities participating in the Society for Vascular Surgery's TCAR Surveillance Project mandates the use of FDA-cleared transcarotid flow reversal neuroprotection devices and FDA-approved transcarotid stents. We are currently the only company to have obtained transcarotid FDA labeling, thereby offering the only transcarotid devices currently eligible for CMS reimbursement coverage through the Society for Vascular Surgery's TCAR Surveillance Project.

- **Procedure-focused approach to product innovation and service.** Our product portfolio was developed to support the technical aspects of TCAR and is currently the only suite of devices specifically designed for carotid access through the neck, or the transcarotid approach. Our research and development strategy strives to optimize safety, effectiveness and ease-of-use through a family of integrated products designed to minimize the learning curve and drive adoption by physicians. In addition, our commercial organization is clinically consultative and trained in many aspects of carotid artery disease treatment, from patient selection and pre-operative planning to procedural support and post-operative care. As a result, our commercial organization provides a level of service and support that we believe is valued by our physician customers and drives customer loyalty.

- **Strong relationships and engagement with key medical societies and governmental agencies.** We have developed strong working relationships with key groups including the FDA, CMS, and the Society for Vascular Surgery. By listening and responding to the needs of key stakeholders, we believe we have been able to achieve efficient regulatory approval timelines, coverage and alignment with key medical societies in the vascular field regarding the benefits of TCAR. We believe our approach to engaging these key stakeholders will continue to help drive our business success.

- **Broad intellectual property portfolio.** As of December 31, 2018, we held 47 issued patents globally that include device, apparatus and method claims surrounding TCAR and our suite of current and potential future products, as well as for treating other vascular diseases and enabling other transcarotid procedures, primarily directed at acute ischemic stroke, other neurovascular procedures, repair of the aorta and transcatheter aortic valve repair, or TAVR. In addition, we believe that our trade secrets, including manufacturing know-how, provide additional barriers to entry.

- **Industry-experienced senior management team**. Our senior management team consists of seasoned medical device professionals with deep industry experience. Our team has successfully lead and managed dynamic growth phases in organizations and commercialized products in markets driven by converting open surgical procedures to endovascular alternatives and expanding access to new procedures for patients. Members of our team have worked with well-regarded medical technology companies such as Boston Scientific, Medtronic, Abbott, Johnson & Johnson, Stryker, Cardinal and Roche.

## Our Market Opportunity

***The Burden of Stroke***

Stroke is a disease that affects the arteries leading to and within the brain. There are two key types of stroke: an ischemic stroke, which occurs when a blood vessel that carries oxygen and nutrients to the brain is blocked by a clot, and a hemorrhagic stroke, which occurs when one of these same blood vessels ruptures. If blood flow is stopped for more than a few seconds, the brain is deprived of oxygenated blood and brain cells can die. Depending on where in the brain the stroke occurs, the consequences of stroke can include difficulty talking, memory loss, cognitive issues, paralysis or loss of muscle movement, inability to attend to bodily needs or care, pain, emotional problems, and death.

Although stroke is often considered preventable, it remains one of the most catastrophic and common conditions worldwide. The American Heart Association, or AHA, estimated that the global prevalence of stroke was 42.4 million in 2015, with ischemic strokes representing approximately 87% of the total number of strokes in the U.S. and approximately two thirds of all strokes worldwide. According to a 2013 study published in the Neuroepidemiology journal, there are an estimated 6.9 million new or recurrent ischemic strokes globally each year. The AHA expects the incidence of stroke to more than double between 2010 and 2050 as demographic trends contribute to an increase in the prevalence of disease states that are commonly associated with strokes.

In the United States, stroke is a major contributor to long-term disability and mortality and disproportionately affects women, the elderly and certain ethnic populations. According to the AHA, stroke was the fifth leading cause of death in the United States in 2014, and results in the death of approximately 140,000 people each year. Stroke ranked in the top 10 most expensive conditions for Medicare, Medicaid, and private insurers in 2013, and according to the AHA, direct medical stroke-related costs will more than double in the United States, from $36.7 billion in 2015 to $94.3 billion in 2035.

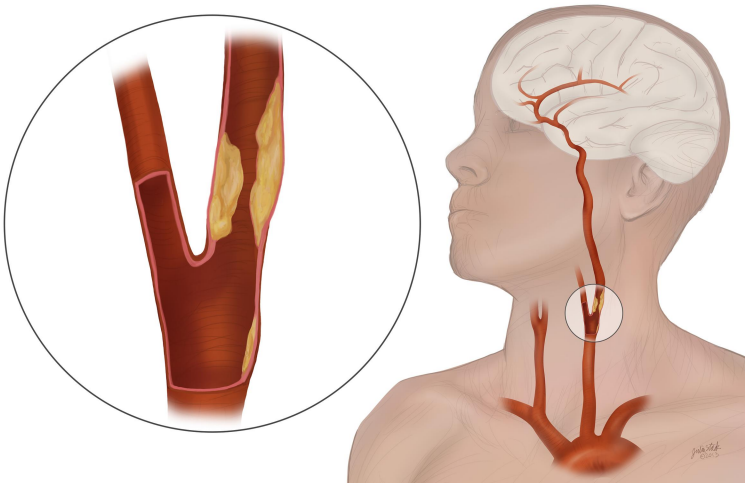
We believe the best way to mitigate the mortality, morbidity and cost burden of stroke is to prevent strokes in the first place. While strokes can be caused by a wide variety of conditions, the Society for Vascular Surgery estimates that carotid artery disease is the primary cause of up to one-third of strokes.

Based on AHA's estimated 690,000 ischemic strokes in the United States every year, carotid artery disease is the cause of up to 230,000 ischemic strokes annually. Clinical evidence has demonstrated that with proper diagnosis and treatment, stroke due to carotid artery disease is mostly preventable.

***Overview of Carotid Artery Disease***

Carotid artery disease, also known as carotid artery stenosis, is the narrowing of the carotid arteries that reside in the neck, one on each side, which are two of the four main blood vessels that supply oxygen to the brain. The narrowing of the carotid arteries is usually caused by atherosclerosis, which is the buildup of cholesterol, fat, calcium and other substances on the walls of arteries. Over time and as people age, an area of atherosclerotic plaque, also called a lesion, is formed. Plaque buildup can lead to narrowing or blockage in the carotid artery, often at the bifurcation of the common carotid and internal carotid arteries.

Carotid plaques in particular are often unstable or crumbly, and a piece of plaque or a blood clot, known as emboli, can break away from the wall of the carotid artery, travel through the bloodstream and get stuck in one of the brain's smaller arteries. When these arteries experience an interrupted or seriously reduced blood supply, the surrounding cells and tissue are deprived of oxygen leading to an ischemic stroke.



***Diagnosis and Referral Pathways for Carotid Artery Disease***

Based on data from Modus Health Group, carotid artery disease was prevalent in approximately 4.3 million people in the United States in 2018, which represented approximately 1.7% of the adult population in 2018, and reflects an increase in prevalence from approximately 4.1 million people in the United States in 2017. Prevalence generally increases with age. Unfortunately for many patients, carotid artery disease is frequently asymptomatic, or silent, and the first symptom is often a stroke. In 2018, an estimated 427,000 patients in the United States were diagnosed with carotid artery disease severe enough to warrant treatment, reflecting an increase from an estimated 403,000 patients in 2017. Patients are diagnosed with carotid artery disease either because they have been non-invasively screened for the disease or they have experienced symptoms ranging from a major or minor stroke to a transient ischemic attack, or TIA, in which neurologic symptoms resolve within 24 hours.

For asymptomatic patients, a primary care physician or a specialist such as a vascular surgeon or cardiologist may screen for carotid artery disease based on the presence of risk factors, including age, family history, history of smoking, high cholesterol, high blood pressure, obesity, diabetes or atherosclerosis in other areas like the heart and legs. When a potential carotid stenosis is detected, the physician will typically refer the patient to a vascular laboratory for a non-invasive ultrasound to definitively diagnose the presence and degree of stenosis, or narrowing of the artery. The degree of stenosis is reported as a percentage of the vessel diameter. There is a correlation between higher degrees of stenosis and increased risk of stroke.

Symptomatic patients who have survived a stroke or experienced a TIA are typically referred to a neurologist for care and physiological assessment. If the patient is found to have underlying carotid artery stenosis, the neurologist will typically refer the patient to a vascular surgeon for urgent treatment to prevent a recurrent stroke. The majority of patients in the United States who are referred for a carotid revascularization procedure receive care from a vascular surgeon.

Once a patient is diagnosed with carotid artery disease, the treatment paradigm is influenced by the patient's symptom status, disease progression and degree of stenosis, as well as factors that may place them at higher risk of adverse events, including their age, anatomic characteristics, and co-morbidities such as cardiovascular and respiratory disease. Patients diagnosed with carotid artery disease are recommended for treatment with medical management, which includes pharmaceutical treatments and lifestyle modifications such as smoking cessation and control of diabetes, hypertension and lipid, or fatty acid, abnormalities. As the degree of stenosis increases, carotid revascularization procedures may also be prescribed. For example, published guidelines by the Society for Vascular Surgery recommend that symptomatic patients be treated with CEA if they present with carotid artery stenosis greater than or equal to 50%. For asymptomatic patients, the guidelines recommend CEA for stenosis greater than or equal to 60%, provided that the risk of stroke and death within 30 days of the procedure is below 3% and life expectancy is greater than three years. The risk of stroke and death within 30 days is subjective and typically depends on the patient's surgical risk factors as well as the skill and experience of the treating physician. The guidelines for CAS procedures are more limiting than those for CEA procedures due primarily to the increased stroke risk associated with CAS.

In 2018, of the estimated 4.3 million individuals in the United States with carotid artery disease, and approximately 427,000 patients that were newly diagnosed, approximately 168,000 patients were treated with a revascularization procedure, representing an approximately 6% increase in newly diagnosed patients relative to 403,000 patients in 2017, and an approximately 10% increase in revascularization procedures relative to approximately 152,000 procedures in 2017. The remaining patients are managed medically and monitored to assess the progression of stenosis and any new or recurrent neurologic symptoms.

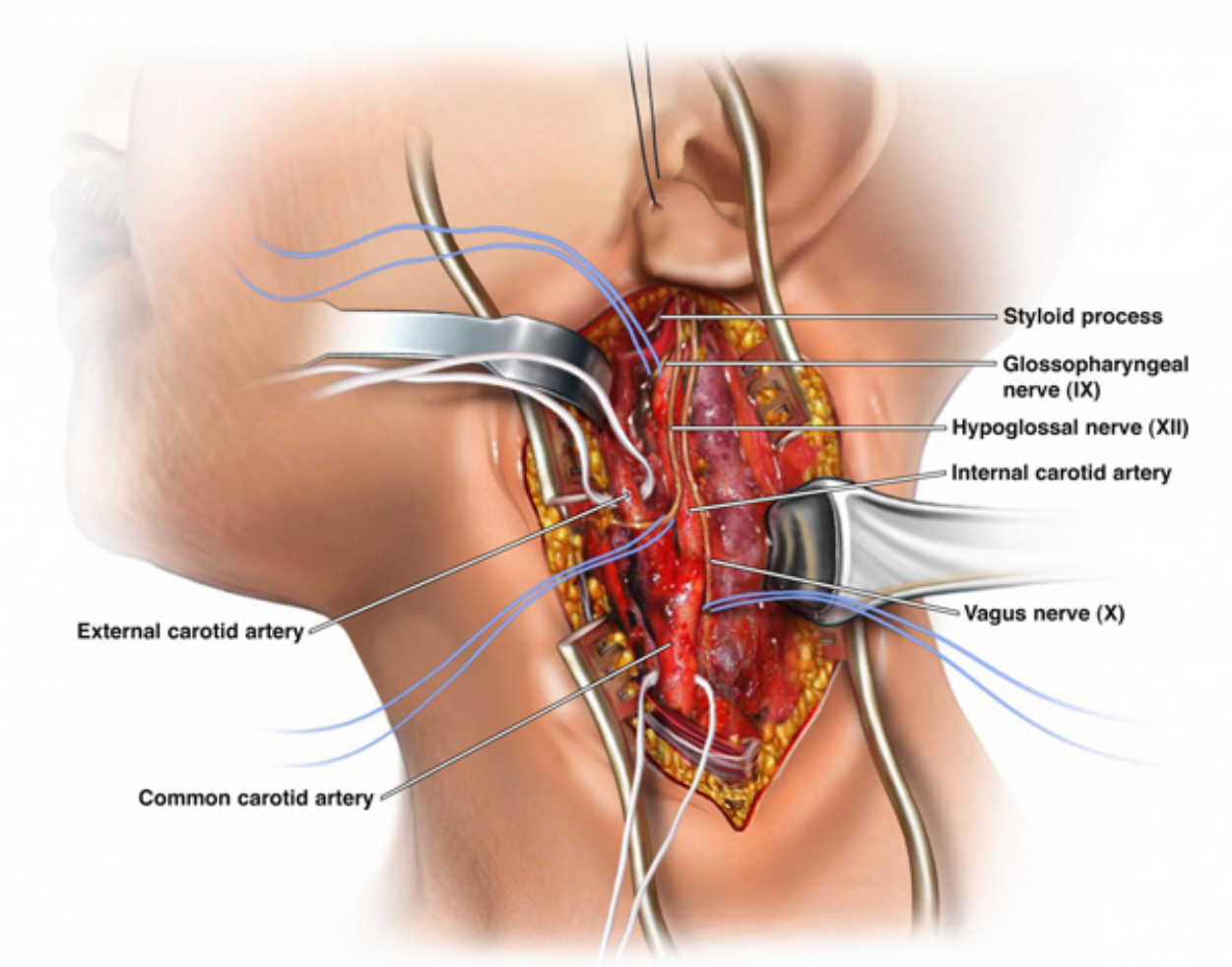
***Existing Alternatives for Carotid Revascularization and Their Limitations***

Existing treatment options for carotid revascularization procedures include CEA and CAS. Both surgical removal of plaque with CEA and stenting of plaque with CAS have demonstrated clinical effectiveness in reducing long-term stroke risk, which is stroke occurring more than 30 days after the procedure. This has shown in multiple randomized trials across different surgical techniques and stent designs, including multi-year follow ups that, in some cases, extend out to 10 years. However, traditional methods of carotid revascularization, including CEA and CAS, have been associated with adverse events within 30 days.

***Carotid Endarterectomy, or CEA***

CEA, which was first performed in 1953, is an invasive surgical procedure, typically performed under general anesthesia. The procedure involves a ten- to fifteen-centimeter incision extending from the base of the neck towards the earlobe, followed by the meticulous dissection of multiple tissue and muscle

layers to open and expose the internal, external and common carotid arteries, collectively known as the carotid bifurcation. During the surgical exposure of the carotid bifurcation, great care is required to avoid damaging the cranial nerves that travel in and around the carotid arteries and related veins. Damage to these nerves, which control functions like speaking, swallowing, facial sensation, taste and saliva production, is a potential side-effect of CEA and can result in transient and permanent quality of life issues and stroke-like symptoms.




Once the bifurcation is exposed, the carotid arteries are then clamped above and below the disease, temporarily halting blood flow to the brain from that artery, so that the artery can be cut open to remove the plaque. Due to the length of the surgery, a shunt is sometimes placed to allow blood flow to bypass the clamped arteries and reach the brain. After the plaque is removed, the artery is closed, and the vessels are unclamped to restore blood flow. The long incisional wound is then sutured closed, though the resulting scar presents a cosmetic disadvantage.

Data from large randomized clinical trials have demonstrated that CEA in addition to medical management is more effective at reducing long-term stroke risk than medical management alone, which has established CEA as the standard of care. Importantly, many of these trials primarily included standard surgical risk patients who were relatively young, free of co-morbidities and deemed reasonably able to withstand the stress of an invasive surgery.

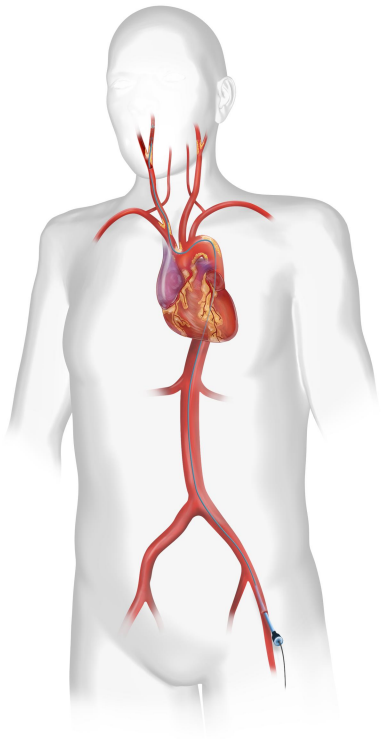
Data from these trials and other studies, including real world registries, have indicated that the surgical impact from a large incision combined with factors such as procedure time, general anesthesia

and patient-specific risk factors can result in known adverse events, including nerve injury, heart attack and even stroke and death. CEA also presents a risk of wound complications, including bleeding and infection, and leaves behind a significant scar. These adverse events can also lead to long hospital stays that are costly to providers and payers. Further, patient recovery times can be significant after a major vascular surgery like CEA.

***Transfemoral Carotid Artery Stenting, or CAS***

To address the invasiveness of CEA, in the 1990s physicians and medical device companies developed CAS, which uses minimally-invasive techniques to place a stent in the carotid artery. The first carotid stents were approved by the FDA in 2004 for high surgical risk patients, marking the beginning of the CAS market in the United States.

In a CAS procedure, a small puncture is made in the groin and a sheath is inserted through which a physician can navigate catheters. The physician navigates the catheters inside the body through approximately three feet of vessels and arteries of the leg, abdomen, chest and neck, up to and often beyond the lesion itself, in order to place a stent to brace the plaque and prevent it from embolizing. Significant technical skill is required to maneuver catheters through these vessels and their twists and turns. Patients may also have significant atherosclerotic disease along the navigation pathway, and the catheters can scrape the inner lining of the arteries and dislodge plaque and embolic debris, which can travel to the brain and cause neurologic injury or stroke during or after the procedure. While embolic protection devices, which are designed to capture debris dislodged during the procedure, may be used to reduce these risks, the brain is not protected while they are maneuvered into place, and they do not always safely capture all debris once in position.



While CAS is less invasive than CEA, multiple randomized clinical studies and real-world registries have consistently shown an almost two-fold increase in the risk of stroke within 30 days relative to CEA.

CAS has also been clinically demonstrated to result in showers of microemboli to the brain, which can cause neurologic injuries including memory loss as well as cognitive decline and dementia while increasing the risk of future stroke. The procedure-related stroke risks are further elevated in elderly, female, symptomatic and other at-risk patients who tend to have smaller or more distended and diseased vessels. As a result, CAS is performed in a minority of carotid revascularization procedures, representing only 14% of the estimated 168,000 carotid procedures performed in the United States in 2018. By contrast, after multiple decades of technology innovation and clinical development, minimally-invasive endovascular procedures targeted at arterial diseases in the legs, abdomen, heart and brain have become the standard of care and represented approximately 70% to 85% of procedures in other areas of the vasculature in 2012 as compared to open surgical alternatives.

***Major Trials Comparing CEA and CAS***

The principal clinical trial evaluating CEA and CAS is the Stenting versus Endarterectomy for Treatment of Carotid-Artery Stenosis trial, known as CREST. CREST was a multi-center randomized controlled trial in the United States that compared CEA to CAS in symptomatic and asymptomatic patients deemed to be at standard risk for adverse events from CEA, or standard surgical risk. This trial, which by protocol excluded high surgical risk patients, was sponsored by the National Institutes of Health and is considered by many physicians to be the landmark trial comparing CEA and CAS. A number of other randomized controlled trials have further established the basis of comparison between CEA and CAS. In addition, post-market registries sponsored by the Society for Vascular Surgery have assessed CEA and CAS in real world practice. Results comparing CEA and CAS from the CREST trial and the Society for Vascular Surgery registry are shown in tables below. In our presentation of the results of the CREST trial, we have indicated incidence rates in percentage terms, regardless of sample size. Statistically significant differences are demonstrated by p-values of less than 0.05, which is the commonly accepted threshold for statistical significance. This follows the convention of standard clinical practice.

***CREST Trial Results***

| | | | 30-day Stroke | | 30-day Stroke/Death | | 4 Year Ipsilateral Stroke | |
|---|---|---|---|---|---|---|---|---|
| **Patient Cohort** | | | **Incidence** | **p-value** | **Incidence** | **p-value** | **Incidence** | **p-value** |
| All Patients | CEA | n=1,240 | 2.3% | 0.01 | 2.3% | 0.005 | 1.7% | NR |
| | CAS | n=1,262 | 4.1% | | 4.4% | | 1.6% | |
| Asymptomatic | CEA | n=587 | 1.4% | 0.15 | 1.4% | 0.15 | 0.9% | NR |
| | CAS | n=594 | 2.5% | | 2.5% | | 1.5% | |
| Symptomatic | CEA | n=653 | 3.2% | 0.043 | 3.2% | 0.019 | 2.5% | NR |
| | CAS | n=668 | 5.5% | | 6.0% | | 1.7% | |
| Male | CEA | n=823 | 2.4% | 0.26 | 2.4% | 0.13 | 1.3% | NR |
| | CAS | n=807 | 3.3% | | 3.7% | | 1.6% | |
| Female | CEA | n=417 | 2.2% | 0.013 | 2.2% | 0.013 | 2.4% | NR |
| | CAS | n=455 | 5.5% | | 5.5% | | 1.5% | |
| Age ≥75 years | CEA | n=353 | 3.1% | 0.035 | 3.7% | NR | 1.4% | NR |
| | CAS | n=333 | 6.9% | | 8.1% | | 3.0% | |
| Age <75 years | CEA | n=887 | 2.0% | NR | 2.1% | NR | 1.8% | NR |
| | CAS | n=929 | 3.1% | | 3.6% | | 1.1% | |

NR - p-values not reported; rates are manually calculated from data presented in the respective publications.

While there was a statistically significant difference in 30-day stroke and 30-day stroke/death favoring CEA, CAS had a significantly lower rate of myocardial infarction of 1.1% compared to CEA at 2.3%, with a p-value equal to 0.03. We believe that this can be largely attributed to the more invasive nature of CEA.

In the FDA analysis of CREST which led to FDA approval of a carotid stent for use in standard surgical risk patients, the rate of acute cranial nerve injury was a secondary endpoint. Patients with an acute cranial nerve injury were evaluated again at the 6-month follow-up visit to determine if the injury persisted. As shown in the table below, patients randomized to the CEA arm had a statistically significant higher rate of acute cranial nerve injury, many of which persisted at the 6-month evaluation. Eighty percent of the cranial nerve injuries involved a motor deficit, such as difficulty swallowing.

| **Cranial Nerve Injury** | **CEA** | **CAS** | **p-value** |
|---|---|---|---|
| | n=1,176 | n=1,131 | |
| Cranial Nerve Injury *(Acute)* | 5.3% | 0.0% | <0.0001 |
| Cranial Nerve Injury *(Persisting at 6 months)* | 2.1% | 0.0% | <0.0001 |

In an analysis of patients who received their randomized treatment assignment without crossover, CEA procedure time was more than twice that of CAS. Additionally, CEA patients had a hospital length of stay of 3.0 days compared to 2.6 days for CAS patients. The difference in hospital length of stay was statistically significant.

| **Procedural Information** | **CEA** | **CAS** | **p-value** |
|---|---|---|---|
| | n=1,193 | n=1,213 | |
| Mean procedure time (mins) | 171 | 69 | NR |
| Length of stay (days) | 3.0 | 2.6 | 0.011 |

In a publication of the primary long-term endpoint of post-procedural ipsilateral stroke, or a stroke on the same side as the original carotid revascularization procedure, over the 10-year follow-up period, ipsilateral stroke occurred in 6.9% of CAS patients and 5.6% of CEA patients. The difference was not statistically significant. Furthermore, there was no statistical difference when outcomes were analyzed separately for symptomatic and asymptomatic patients. There was also no statistical difference between CAS and CEA at any other year of follow-up from year one through year nine. These data demonstrate that both CAS and CEA provide the same durable reduction of long-term stroke risk.

***Society for Vascular Surgery Vascular Registry***

In 2013, members of the Society for Vascular Surgery Vascular Registry, the precursor to the VQI, published outcomes for CEA and CAS in high surgical risk patients using CMS high risk criteria per the National Coverage Determination. The objective of the analysis was to determine objectively if the CMS high risk criteria demonstrated differential and biased outcomes in CEA and CAS due to the over-representation of high risk patients for CAS. The authors also sought to determine if the rate of adverse events in high risk patients is lower in CAS than CEA as the surgical high risk criteria would suggest. The primary endpoint was a composite of stroke, death and myocardial infarction at 30 days. In a risk adjusted analysis, CAS had a significantly higher rate of stroke, death and myocardial infarction compared to CEA. For the high risk cohort, the rates of stroke for CEA and CAS were 3.6% and 4.9%, respectively; the rates of stroke and death for CEA and CAS were 4.8% and 6.2%, respectively.

| | CEA High Risk | | | CAS High Risk | | |
|---|---|---|---|---|---|---|
| | Symptomatic | Asymptomatic | All | Symptomatic | Asymptomatic | All |
| | n=936 | n=1,418 | n=2,354 | n=1,538 | n=1,844 | n=3,382 |
| Stroke/death/ myocardial infarction | 7.3% | 5.0% | 5.9% | 9.1% | 5.4% | 7.1% |
| Stroke/death | 6.4% | 3.7% | 4.8% | 7.9% | 4.8% | 6.2% |
| Stroke | 4.9% | 2.7% | 3.6% | 6.7% | 3.4% | 4.9% |

## Our Solution

With our portfolio of TCAR products, we have pioneered a new approach for the treatment of carotid artery disease and are seeking to establish TCAR as the standard of care. TCAR is a minimally-invasive solution that addresses the morbidity of CEA and the 30-day stroke risk of CAS, while providing a reduction in long-term stroke risk. We believe that by meeting the standard of brain protection and reduction in 30-day and long-term stroke risk afforded by CEA in a minimally-invasive manner, TCAR offers an attractive alternative for patients, providers and payers and will be able to successfully penetrate the carotid revascularization market. We also believe that physicians and patients will consider TCAR with medical management as an alternative to medical management alone as further clinical evidence and experience accrues.

***Transcarotid Artery Revascularization, or TCAR***

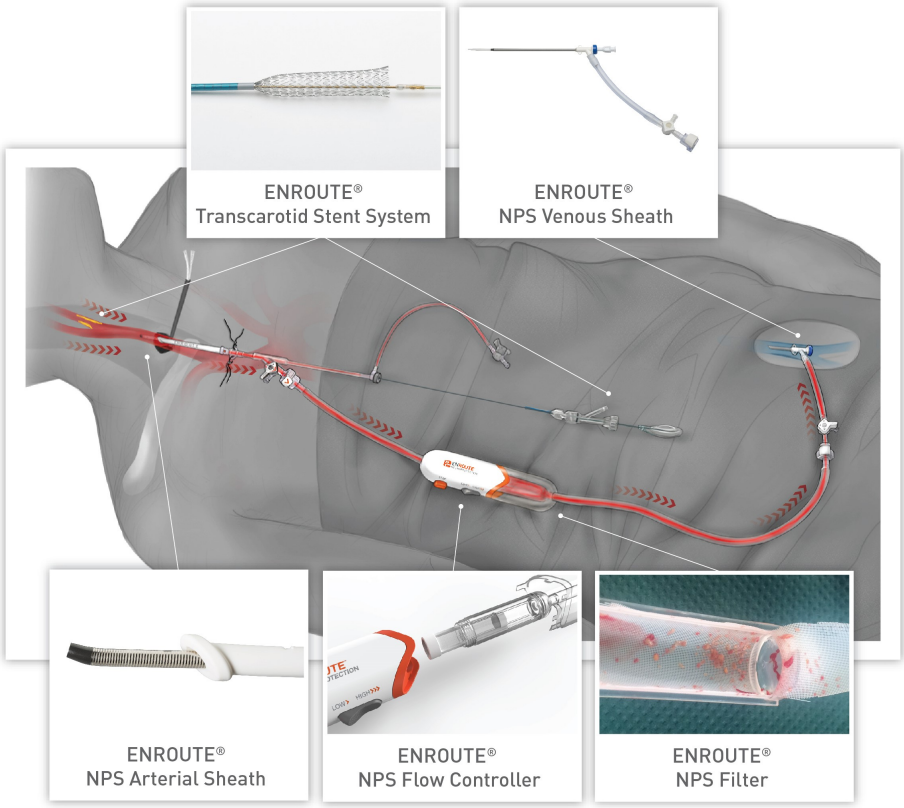
TCAR relies on two novel concepts: minimally-invasive direct carotid access in the neck, and high-rate blood flow reversal during the procedure to protect the brain.

The TCAR procedure begins with a two- to three-centimeter incision slightly above the collarbone, thereby obviating the need to maneuver catheters from the groin. The incision is made just above the collarbone to expose a small section of the carotid artery well below the carotid stenosis and most of the cranial nerves. A puncture is made into the carotid artery using our transcarotid access kit, and our proprietary sheath is placed inside the carotid artery. This sheath is connected to the rest of our flow reversal system, which lies outside the body, and ends in a connection to our venous sheath in the patient's groin. After the carotid artery is clamped just below the sheath, the pressure gradient between the high-pressure arterial system in the neck and the low-pressure venous system in the groin creates the blood flow reversal, which redirects dislodged plaque and debris away from the brain where it is captured in an external filter in our system.

While the brain is protected by flow reversal, our guidewire is navigated across the lesion and our transcarotid stent is delivered and placed in the carotid artery to stabilize the plaque against the wall of the artery, trapping the lesion and reducing the risk of a future stroke. The short distance enabled by our

transcarotid access allows for accurate stent placement. Balloon catheters can also be used to pre-dilate the lesion or further expand the stent when appropriate. Any debris released during these steps of the procedure is directed safely away from the brain by the flow reversal. Clinical studies have shown that patients can tolerate this temporary redirection of blood flow, which usually lasts for approximately ten minutes, due to the redundant network of arteries in the brain that enable it to receive blood flow and oxygen through multiple pathways. After our transcarotid stent is implanted, the blood flow is returned to normal, the system is removed, and the artery and small wound are sutured closed.

The following diagram depicts our portfolio of TCAR products:




***Key Clinical Advantages of TCAR***

We believe the key advantages of TCAR relative to CEA and CAS include:

- ***Reduction in stroke risk.*** In our pivotal ROADSTER clinical trial, TCAR demonstrated a 30-day stroke rate of 1.4% in 141 high surgical risk patients. In the study publication from the Journal of Vascular Surgery in November 2015, the authors reported that the 30-day stroke rate of 1.4% was the lowest reported for any prospective, multicenter trial of carotid artery stenting. In addition, although we have not conducted any head-to-head studies comparing TCAR to CAS or CEA, in November 2018, we became aware that the Society for Vascular Surgery reported data from the TCAR Surveillance Project regarding 2,545 TCAR procedures, which showed a statistically significant reduction in the rate of in-hospital stroke, and stroke and death, as compared to data from 9,460 CAS patients, and a statistically equivalent reduction in in-hospital

stroke, and stroke and death, as compared to data from 43,114 CEA patients, despite TCAR patients being older and sicker than CEA patients.

- ***Low surgical morbidity***. The minimally-invasive nature of TCAR offers inherent advantages that can mitigate adverse events typically associated with CEA, including cranial nerve injury and myocardial infarction. Data from the Society for Vascular Surgery's TCAR Surveillance Project from 2,545 TCAR procedures showed a statistically significant ten-fold reduction in the rate of cranial nerve injury as compared to data from 43,114 CEA patients. Similarly, data from our ROADSTER study indicated that TCAR had a heart attack rate of 0.7% in high surgical risk patients within 30 days of the procedure. CREST data regarding standard surgical risk patients showed a 30-day heart attack rate of 2.3% and 1.1% for CEA and CAS, respectively.

- ***Minimal patient discomfort and rapid recovery.*** While the typical incision required for CEA is ten to fifteen centimeters long, the TCAR incision is generally two to three centimeters long, leaving behind a much smaller wound and scar that often only requires non-opioid pain medications and little more than a steri-strip to cover the operative wound. In our ROADSTER clinical study, 53% of TCAR procedures were performed under local anesthesia. In addition, real-world data from the Society for Vascular Surgery's TCAR Surveillance Project showed a statistically significant reduction in the likelihood that a TCAR patient would require a hospital stay in excess of one day as compared to a CEA patient.

- ***Reduction in the risk of microembolic debris.*** While large emboli have dominated clinical focus and discussion due to the ability to cause clinically diagnosed stroke or TIAs, there is a growing body of evidence that indicates that showers of micro emboli to the brain, which, for example, may be caused by the CAS procedure, can cause neurologic injuries including memory loss, cognitive decline and dementia, while increasing the risk of future stroke. Data from our PROOF clinical trial indicated that only 18% of studied TCAR patients presented with new white lesions occurring on the same side of the brain, or ipsilateral, as the treated carotid artery, as shown on diffusion-weighted magnetic resonance imaging studies. This rate of new white lesions, which indicate brain injury, was comparable to published data for CEA procedures and significantly lower than published data for CAS procedures, which show a range of 45% to 87% of patients with new white ipsilateral lesions.

We believe the results of our clinical studies provide evidence that TCAR may offer significantly better reduction in stroke risk than CAS and similar reduction in stroke risk compared to CEA, the current standard of care for carotid revascularization, allowing physicians to present the minimally-invasive alternative of TCAR to patients without compromising the reduction in stroke risk they would expect in a CEA procedure. We believe the growing clinical evidence base from our ongoing and future studies and the Society for Vascular Surgery's TCAR Surveillance Project will continue to drive confidence in the procedure and support continued adoption.

***Benefits to Other Key Stakeholders***

In addition to offering clinical benefits to patients, we believe that TCAR also offers valuable non-clinical benefits for providers and payers relative to CEA and CAS.

***Providers***

We believe TCAR allows for improved hospital workflow given the simplicity, predictability, and efficiency of the procedure as compared to CEA and CAS. By allowing direct access to the carotid artery rather than requiring the physician to navigate the vasculature as in CAS, and allowing the physician to place a stent to trap plaque rather than requiring the time-consuming and physically burdensome surgical removal of carotid plaque as in CEA, we believe TCAR is a more efficient and predictable procedure. Data from the Society of Vascular Surgery's TCAR Surveillance Project has shown that the average

TCAR procedure time has been statistically significantly shorter and that there has been a statistically significant reduction in the percent of hospital stays longer than one day, relative to CEA. These benefits can help hospitals to better utilize their operating room capacity and fixed overhead and reduce the number of procedures associated with hospital stays longer than one day, which have been shown to result in financial losses for the hospital facilities. We believe the economic benefits are further aided by the reduction in expensive adverse events that are borne by capitated providers or absorbed within 90-day global periods related to hospital reimbursement. Through third-party consultants, we have performed economic analyses of TCAR using our own clinical data from the ROADSTER study and published data for CEA surrounding cost inputs for both procedures and national weighted average reimbursement rates. We believe the results of these analyses show that TCAR compares favorably to CEA in terms of hospital margins and economic value proposition for the procedure itself as well as the full length of hospital stay.

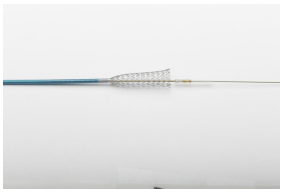
***Payers***

Stroke is one of the costliest conditions for the healthcare system and ranked in the top ten most expensive conditions for Medicare, Medicaid, and private insurers in 2013. By reducing the 30-day stroke risk from the procedure and the long-term stroke risk from the disease after 30 days, we believe that TCAR mitigates the significant cost burden associated with the morbidity of stroke victims. In addition to reducing costs associated with stroke, we believe TCAR also helps to reduce downstream costs associated with rehabilitation of cranial nerve injuries, myocardial infarction, microembolization and other adverse events.

***Our Product Portfolio***

TCAR is enabled by our proprietary portfolio of TCAR products designed to provide direct access to the carotid artery, effective reduction in stroke risk throughout the procedure, and long-term restraint of carotid plaque. In addition to enabling the safety and effectiveness of TCAR, our proprietary products are specifically designed to enable a short learning curve, consistent ease of use and physician comfort. Our products are also currently the only devices cleared and approved by the FDA specifically for transcarotid use.

Today, our product portfolio consists of the following four single use components. Based on our experience, the full product portfolio is used in the majority of TCAR procedures. In the future we plan to continue to expand our product portfolio to include additional tools and devices to support the TCAR procedure.

| | | |
|---|---|---|
| *ENROUTE Transcarotid Neuroprotection System* |  | • Used to directly access the common carotid artery and initiate temporary blood flow reversal<br>• Allows for flow modulation enabling lesion imaging and patient tolerability<br>• Only FDA-cleared transcarotid neuroprotection system |
| *ENROUTE Transcarotid Stent System* |  | • Self-expanding, self-tapering stent with clinical data regarding lasting safety outcomes<br>• Transcarotid delivery system improves the accuracy and the overall ergonomics of the TCAR procedure<br>• Only FDA approved transcarotid stent system |
| *ENHANCE Transcarotid Peripheral Access Kit* |  | • Used to gain initial access to the common carotid artery<br>• Only access kit specifically designed for use in the common carotid artery |
| *ENROUTE 0.014" Guidewire* |  | • Main conduit for navigating and crossing the target lesion for delivery of interventional devices<br>• Short working length and proprietary tip designed for TCAR |

Our ENROUTE NPS and ENROUTE stent are FDA cleared and approved, respectively. The ENROUTE NPS is cleared for transcarotid vascular access, introduction of diagnostic agents and therapeutic devices, and embolic protection during carotid artery angioplasty and stenting procedures for patients diagnosed with carotid artery stenosis and who have appropriate anatomy, and the ENROUTE stent is approved for use in conjunction with the ENROUTE NPS for the treatment of patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization and meet certain criteria.

## Our Target Market

We are working to establish TCAR as the preferred alternative to both CEA and CAS for the treatment of patients with carotid artery disease. Because TCAR offers clinically proven, minimally-invasive reduction in stroke risk, we believe that TCAR offers a better solution for the approximately 168,000 patients treated in the United States in 2018, most of whom were treated with either CEA or CAS, which we estimate to be a near-term market conversion opportunity greater than $1.0 billion. Additionally, we believe that as our technology becomes more widely adopted, TCAR may become a compelling alternative for patients that are treated with medical management alone each year. As a result, we believe the potential addressable opportunity for TCAR includes the approximately 427,000 individuals in the United States who were diagnosed with carotid artery disease in 2018, representing a total U.S. target market opportunity of approximately $2.6 billion in 2018.

Currently, our ENROUTE stent is indicated for use in patients who are considered high surgical risk, and either are symptomatic with greater than or equal to 50% stenosis or are asymptomatic with greater than or equal to 80% stenosis. The labeled indications for use for our other products, including the ENROUTE NPS, are agnostic to surgical risk status. Based on the FDA label of high surgical risk for our stent, CMS provides reimbursement coverage for TCAR in patients who are considered a high surgical

risk but not standard surgical risk. According to published studies and primary research, we believe the high surgical risk population represents approximately two-thirds, or over 111,000, of the approximately 168,000 patients treated for carotid artery disease in the United States in 2018, most of whom were treated with either CEA or CAS. We are currently focused on clinical development activities to support label expansion for our ENROUTE stent to standard surgical risk patients. We would then seek an associated expansion in CMS reimbursement coverage.

While our current commercial focus is on the U.S. market, our ENROUTE NPS and ENROUTE stent have obtained CE Mark approval, allowing us to commercialize in Europe in the future. We intend to pursue regulatory clearances in China, Japan, and other select international markets. Carotid artery disease and stroke are prevalent, devastating and costly conditions worldwide, and we estimate that a significant opportunity exists for TCAR outside the United States, since the United States represents only 10% of the estimated global incidence of ischemic stroke.

## Our Growth Strategy

Our mission is to be the global leader in the treatment of carotid artery disease. We seek to establish TCAR as the standard of care for carotid revascularization by converting the base of existing CEA and CAS procedures and expanding the market to include patients treated with medical management alone. Our growth strategies include:

- ***Strategically expanding our U.S. sales force and marketing activities***. As of December 31, 2018, we have approximately 400 hospital accounts across 25 territories. To date, we have taken a measured approach to account targeting and physician training. Over time, we plan to selectively add highly qualified personnel to our commercial organization with a strategic mix of selling professionals and clinical specialists to cover the concentrated group of approximately 2,750 physicians and 750 hospitals that we believe perform 80% of carotid revascularization procedures. As we grow the size of our U.S. sales organization, we plan to remain focused on educating hospitals and physicians regarding TCAR, which we believe will increase the adoption of TCAR in existing hospital accounts while expanding our new account and trained physician base.

- ***Scaling professional education to drive physician use.*** As of December 31, 2018, we have trained approximately 775 physicians in the United States. Our education and training courses are led by a highly regarded faculty of key opinion leaders in vascular surgery, allowing for significant peer-to-peer interaction and influence from experienced TCAR practitioners. These courses have been fully subscribed since inception. We believe these professional education initiatives are a key differentiator in driving successful outcomes during the learning curve of TCAR and establishing the confidence physicians need to adopt TCAR. We plan to continue conducting these courses while regionalizing the course locations, continuously improving the program, and expanding our physician faculty.

- ***Increasing TCAR adoption.*** In our existing account and trained physician base, we have shown an ability to drive adoption in high surgical risk patients where CEA might otherwise be riskier or technically challenging, as well as in patients with anatomy or risk factors unfavorable for CAS. Our strategy is to continue educating physicians regarding TCAR across broader patient subgroups as physicians' experience and confidence with the procedure accrues and our clinical evidence base expands through the Society for Vascular Surgery's TCAR Surveillance Project and our ongoing and future studies. We also plan to continue converting CEA or CAS procedures to TCAR in current hospital accounts by training additional physicians in each account.

- ***Building our clinical evidence base***. Vascular surgeons typically rely on clinical evidence to drive changes in their practice. Primary care physicians and specialist referrers like neurologists and cardiologists also scrutinize clinical evidence. We plan to continue to build our clinical evidence base by completing enrollment in ROADSTER 2 and commencing new clinical studies

intended to support marketing efforts and regulatory initiatives. We also expect the Society for Vascular Surgery's ongoing TCAR Surveillance Project registry to continue to grow and produce valuable presentations and published papers with comparative data and sub-group analyses that will further define the role of TCAR across patient populations.

- ***Broadening the indication for the ENROUTE stent and expanding reimbursement.*** We plan to continue to work to expand FDA labeling for the ENROUTE stent to address the approximately one-third of treated patients who are standard surgical risk. If we obtain approval of a label expansion, we intend to pursue Medicare coverage for TCAR in standard surgical risk patients.

- ***Pursuing international markets.*** Carotid artery disease and stroke are prevalent, devastating and costly conditions worldwide, and we estimate that a significant opportunity exists for TCAR outside the United States. We currently have CE Mark for the ENROUTE NPS and ENROUTE stent, which would allow us to commercialize in Europe in the future. We are also actively working towards regulatory clearances for our products in China and Japan.

- ***Continuing our history of innovation in and beyond TCAR.*** We are currently developing additional and next generation products to support and improve TCAR to meet the evolving needs of physicians and their patients. We also have a broad intellectual property platform and, in the future, we intend to leverage our expertise and the physiologic and engineering advantages made possible by our transcarotid approach to develop new products targeting procedures and vascular disease states in the heart, aortic arch and brain.

## Clinical Data

The safety, effectiveness and clinical advantages of TCAR have been observed in multiple clinical trials and post-market studies that have collectively evaluated more than 3,500 patients in the United States and Europe to date. Our first-in-human trial, the PROOF Study, was initiated as a feasibility study to assess the safety and performance of the ENROUTE NPS and later was expanded to support CE marking of the ENROUTE NPS. Data from the PROOF Study were also used to support FDA approval of the investigational device exemption, or IDE, for the ROADSTER Study. Data from the pivotal cohort of the ROADSTER Study supported FDA 510(k) clearance of the ENROUTE NPS, and a subset of the data supported pre-market, or PMA, approval of the ENROUTE stent. The results of the pivotal phase of the ROADSTER study were published in November 2015 in the Journal of Vascular Surgery. We are currently conducting a post market approval study, ROADSTER 2, to evaluate the outcomes in TCAR procedures using the ENROUTE stent used in conjunction with the ENROUTE NPS in broader, "real-world" use in a minimum of 600 patients. Data on TCAR outcomes also continues to accrue through the Society for Vascular Surgery-sponsored TCAR Surveillance Project, an ongoing real-world, open-ended registry which includes over 3,500 patients treated with TCAR as of December 31, 2018 and over 2,500 TCAR procedures reported on since its initiation in September 2016.

***Summary of Key Clinical Trials***

| | PROOF | ROADSTER | ROADSTER 2 | TCAR Surveillance Project |
|---|---|---|---|---|
| **Study Type** | First in Human<br>CE Marking<br>DW-MRI Sub-Study | U.S. Pivotal IDE Study | U.S. Post-Approval Study | Real world observation |
| **Patients** | 75 pivotal<br>56 DW-MRI Sub-Study | 141 Pivotal<br>78 Continued Access<br>52 Stent Sub-Study | 600+ | Open Ended |
| **Profile** | High Surgical Risk and Standard Surgical Risk | High Surgical Risk | High Surgical Risk | High Surgical Risk |
| **Status/Publication** | Complete<br>J Endovasc Ther. 2017 Apr;24 (2):265-270 | Complete<br>J Vasc Surg. 2015 Nov;62(5):1227-34 (pivotal cohort only) | Enrolling<br>641 patients to date | Enrolling<br>>2,500 patients to date |
| **Carotid Stent Systems Used** | CE Marked Carotid Stents, including the Cordis Precise Stent | FDA Approved Carotid Stents, including the Cordis Precise Stent | ENROUTE Transcarotid Stent System | ENROUTE Transcarotid Stent System |

***Summary of TCAR Clinical Trial Outcomes***

| | PROOF | ROADSTER - pivotal phase | | ROADSTER - continued access | | Pooled ROADSTER | |
|---|---|---|---|---|---|---|---|
| | ITT population | ITT population | Per-protocol | ITT population | Per-protocol | ITT population | Per-protocol |
| **Stroke at 30 days** | | | | | | | |
| All stroke[(1)] | 1.3% | 1.4% | 0.7% | 1.3% | 0.0% | 1.4% | 0.5% |
| All stroke and death | 1.3% | 2.8% | 2.2% | 1.3% | 0.0% | 2.3% | 1.5% |
| **Other adverse events at 30 days** | | | | | | | |
| Myocardial infarction | 0.0% | 0.7% | 0.7% | 2.6% | 1.5% | 1.4% | 1.0% |
| Cranial Nerve Injury *(Acute)* | 2.7% | 0.7% | NR | 0.0% | NR | 0.5% | NR |
| Cranial Nerve Injury *(persisting at 6 months)* | 2.7% | 0.0% | NR | 0.0% | NR | 0.0% | NR |
| **Procedural information** | | | | | | | |
| Mean procedure time (mins ) | NR | 73.6 | NR | 72.4 | NR | 73.2 | NR |
| Mean length of stay *(days)* | NR | 1.9 | NR | 1.4 | NR | 1.7 | NR |

(1) All strokes observed have been minor strokes; No major strokes have been observed.

***PROOF First-in-human Clinical Trial***

Our first-in-human trial, the PROOF Study, was a single-arm trial conducted at one trial site in Europe from 2009 to 2012. The PROOF Study was initiated as a feasibility study to assess the safety and performance of the ENROUTE NPS in a limited number of patients, initially enrolling 10 patients. The PROOF Study was later expanded to 75 patients to collect the clinical data necessary to support CE

marking of the ENROUTE NPS. Data from the PROOF Study were also used to support FDA approval of the IDE for the ROADSTER Study.

The PROOF Study enrolled patients that were classified as high surgical risk, as well as patients classified as standard surgical risk. The results from the PROOF Study demonstrated that TCAR was technically feasible and resulted in a stroke incidence of 1.3% within 30 days, which was significantly lower than that reported for CAS in prior clinical trials.

Additionally, a sub-study of 56 patients underwent pre- and post-procedure diffusion-weighted magnetic resonance image scanning, or DW-MRI, to detect new white lesions on the ipsilateral side of the brain as a sensitive surrogate marker of microemboli and brain injury. The analysis resulted in only 18% of the treatment population presenting with ipsilateral new white lesions, which was also comparable to that reported for CEA in prior clinical trials and significantly less than that reported in prior CAS trials.

***Pivotal ROADSTER Clinical Trial***

Our pivotal trial, the ROADSTER Study, was a single-arm trial conducted at 17 sites across the United States and one site in Europe from 2012 to 2014. The design of the ROADSTER Study, which was used to support FDA 510(k) clearance of the ENROUTE NPS, was largely based upon predicate embolic prevention studies and followed the relevant FDA guidance published in 2008. In the pivotal phase, the ROADSTER study enrolled 141 patients that were classified as being at high surgical risk.

The primary endpoint of the ROADSTER Study was a hierarchical composite of stroke, death or myocardial infarction within 30 days. Key secondary endpoints included acute device, technical and procedural success at 30 days, as well as cranial nerve injury at six months. The results of the ROADSTER Study were analyzed on an “intention to treat,” or ITT basis, as well as a “per protocol,” or PP basis. The ITT results accounted for all patients enrolled in the clinical trial, including patients treated despite major protocol deviations. The PP results included only patients that met all of the inclusion and none of the exclusion criteria and who were compliant with the protocol-mandated study medication regimen. There were no patients lost to follow-up in either the ITT or PP cohorts.

On an ITT basis, the primary endpoint event rate in the pivotal phase of the ROADSTER Study was a 3.5% hierarchical composite rate of stroke, death or myocardial infarction at 30 days, comprised of two strokes, or a 1.4% incidence, two deaths, or a 1.4% incidence, and one myocardial infarction, or a 0.7% incidence. Both deaths were respiratory in nature and were independently adjudicated as not related to the device. There were no site-reported cardiovascular or neurologic deaths, although our independent clinical events committee adjudicated one death as cardiovascular. There were no major strokes. There was one report of an acute cranial nerve injury, representing a 0.7% incidence, which resolved within six months. These data supported FDA 510(k) clearance of the ENROUTE NPS.

In the PP analysis, the primary endpoint event rate was 2.9%, comprised of one stroke, or a 0.7% incidence, two deaths, or a 1.5% incidence, and one myocardial infarction, or a 0.7% incidence.

A continued access phase of the ROADSTER Study was conducted during the time that the 510(k) premarket notification for the ENROUTE NPS was under review by FDA. This phase enrolled an additional 78 patients with the same primary and secondary endpoints as the pivotal phase of the ROADSTER Study. The results of the continued access phase were similar to those reported in the pivotal phase of the ROADSTER study. The ENROUTE NPS was 510(k) cleared by the FDA in February 2015.

Following a pre-submission interaction with the FDA, the FDA permitted data from a sub-analysis of 52 patients in the ROADSTER Study who were treated with the Cordis Precise Pro RX Carotid Stent System to be used, in conjunction with existing data from Cordis on CAS clinical trials performed with the Cordis Precise Pro RX, to support our pre-market approval application for the ENROUTE stent. The

ENROUTE and Precise stent systems share the same design for the stent implant itself, and differ only in the design of the delivery system. Based on this data, the PMA for the ENROUTE stent was approved in May 2015.

We also initiated a separate sub-study of patients treated PP in the ROADSTER pivotal and continued access cohorts to assess the longer-term rate of ipsilateral stroke beyond 30 days. This sub-analysis, which consisted of 164 patients including 112 from the pivotal phase and 52 from the continued access phase, provided insight into the ability of TCAR to limit stroke incidence in longer-term follow-up. At one-year follow-up, the ipsilateral stroke rate was 0.6% and the mortality rate was 3.7% past 30 days.

***ROADSTER 2 U.S. Post Market Approval Study***

The ROADSTER 2 Post Approval Study is a condition of PMA approval for the ENROUTE stent. The study is intended to evaluate the outcomes in TCAR using the ENROUTE stent in conjunction with the ENROUTE NPS in broader, “real world” use. Like the sub-analysis from the ROADSTER Study that led to PMA approval of the ENROUTE stent, the primary endpoint, which is being assessed on a PP basis, is the rate of procedural success at 30 days in high surgical risk patients with a three year minimum life expectancy.

The ROADSTER 2 post approval study must enroll a minimum of 600 patients at a minimum of 30 sites. 70% of the participating sites must be new sites that did not participate in the ROADSTER Study. Enrollment commenced in 2015. Enrollment and final 30-day follow-up assessments are expected to be completed in 2019.

We are required to submit semi-annual, interim reports to the FDA on the progress of, and outcomes for, the ROADSTER 2 Post Approval Study. In our most recent report to the FDA dated November 15, 2018, 550 patients have been enrolled and treated PP. Of those patients, 512 have completed the 30-day follow-up assessment. For those patients completing the 30-day follow-up assessment, the procedural success rate is 98.2%. The rate of procedural success in ROADSTER 2 compares favorably to the rate of procedural success in the combined pivotal and continued access cohorts of the initial ROADSTER study. Other key clinical endpoints include the rates of hierarchical ipsilateral stroke, death and myocardial infarction, cardiac death, neurologic death and cranial nerve injury. These key clinical endpoints in ROADSTER 2 are summarized in the following table:

**ROADSTER 2: key clinical endpoints at 30 days**

| | N=550 |
|---|---|
| **Stroke and death at 30 days** | |
| All stroke | 0.9% |
| All stroke and death | 1.1% |
| **Other adverse events at 30 days** | |
| Ipsilateral Stroke | 0.7% |
| Rate of Death - Cardiac | 0.2% |
| Rate of Death - neurologic | 0.0% |
| Rate of Death - Other | 0.0% |
| Rate of Cranial Nerve Injuries (Acute) | 1.5% |
| Myocardial infarction | 0.9% |
| **Procedural information** | |
| Mean procedure time (mins) | 75.0 |
| Mean length of stay (days) | 1.9 |

***The Society for Vascular Surgery's TCAR Surveillance Project***

The TCAR Surveillance Project was implemented in September 2016 as an initiative of the Society for Vascular Surgery Patient Safety Organization. The TCAR Surveillance Project is an ongoing, open-ended registry that was designed to monitor the safety and effectiveness of transcarotid stents placed directly into the carotid artery while reversing blood flow within the carotid artery. It is intended to compare TCAR with CEA in centers that participate in the Society for Vascular Surgery Vascular Quality Initiative, or VQI. The TCAR Surveillance Project was reviewed by the FDA and deemed to be a scientifically valid extension study of TCAR, thereby allowing CMS to provide coverage within the parameters of the existing National Coverage Determination. The Society for Vascular Surgery VQI is designed to improve the quality, safety, effectiveness and cost of vascular health care by collecting and exchanging information, and it is available to all providers of vascular health care and their respective institutions. Because data from CAS procedures are also collected in the Society for Vascular Surgery VQI, comparisons of TCAR to CAS can also be made.

Eligible patients must meet the inclusion criteria specified for the TCAR Surveillance Project. Generally, patients must be at high surgical risk and must have had their TCAR procedure performed using any FDA-cleared transcarotid proximal embolic protection device utilizing flow reversal, such as our ENROUTE NPS, and any FDA-approved transcarotid stent, such as our ENROUTE stent**.** To date, the ENROUTE stent and the ENROUTE NPS are the only such devices cleared and approved by the FDA. TCAR procedures entered into the Society for Vascular Surgery VQI carotid artery stenting registry for the TCAR Surveillance Project are eligible for reimbursement by Medicare if the patients meet the requirements set forth above. We believe the TCAR Surveillance Project represents a unique collaboration between a physician specialty society, the FDA and CMS. It also marks the first time that CMS has granted broader reimbursement for a stent-based treatment paradigm for carotid artery disease in a registry not managed by industry.

The TCAR Surveillance Project is intended to be a repository for TCAR procedures and outcomes data to broaden the clinical evidence base for TCAR. TCAR is one of many surgical and endovascular procedures that is tracked by the Society for Vascular Surgery VQI. Over time, it is expected that academic researchers will query the database and produce publications in peer review journals, and physicians may present data at industry conferences, regarding the safety and effectiveness of TCAR in real world use.

The primary outcome measure of the TCAR Surveillance Project is one-year ipsilateral stroke or death. The TCAR Surveillance Project also tracks in-hospital stroke, death and myocardial infarction. Other secondary outcomes, such as cranial nerve injury and re-intervention, are also being reported. For the secondary outcome measures, any stroke will be counted and in-hospital stroke events are not limited to the ipsilateral side.

***TCAR Surveillance Project: TCAR vs. CEA***

Contemporaneous comparative outcomes from January 2016 to September 2018 were presented in November 2018 in both unadjusted analyses as well as analyses adjusted for the baseline characteristics of the patient populations. In general, patients treated with TCAR were older than patients treated with CEA, and were more likely to have coronary co-morbidities, renal dysfunction and a prior carotid intervention. Below is a summary of the outcomes presented and the patient demographics in which there was a statistically significant difference between the populations.

**TCAR vs. CEA Unadjusted Outcomes (in hospital)**

| Stroke and other adverse events | TCAR (%) N=2,545 | CEA (%) N=43,114 | P-value |
|---|---|---|---|
| **Major adverse events at 30 days** | | | |
| Stroke/Death | 1.8 | 1.4 | 0.09 |
| Stroke/Death/Myocardial infarction | 2.1 | 1.8 | 0.17 |
| Stroke | 1.4 | 1.2 | 0.27 |
| Death | 0.5 | 0.3 | 0.04 |
| 30-day Death | 0.9 | 0.6 | 0.08 |
| **Other adverse events at 30 days** | | | |
| Myocardial infarction | 0.4 | 0.4 | 0.71 |
| Cranial nerve injury | 0.2 | 2.7 | <.001 |
| Bleeding | 1.4 | 1.0 | 0.05 |
| **Other procedural information** | | | |
| Mean procedure time (mins) | 75.0 | 116.0 | <0.001 |
| Length of stay >1 day | 29% | 32% | <0.01 |

**TCAR vs. CEA Baseline Demographics (% of patients)**

| | TCAR N=2,545 | CEA N=43,114 | P-value |
|---|---|---|---|
| Age | 73.1 + 9.4 | 70.6 + 9.6 | <.001 |
| Female | 36.2% | 39.4% | <.01 |
| Coronary artery disease | 51.3% | 26.9% | <.001 |
| Prior congestive heart failure | 18.8% | 11.2% | <.001 |
| Prior coronary artery bypass grafting | 23.7% | 19.8% | <.001 |
| Prior percutaneous coronary intervention | 28.2% | 22.1% | <.001 |
| Chronic obstructive pulmonary disease | 29.2% | 23.2% | <.001 |
| Glomerular filtration rate<60 | 40.6% | 34.3% | <.001 |
| Current smoker | 23.5% | 25.3% | 0.05 |
| Prior carotid revascularization | 30.7% | 15.0% | <.001 |
| Aspirin | 89.8% | 83.9% | <.001 |
| Antiplatelet | 84.7% | 34.5% | <.001 |
| Statin | 88.3% | 83.4% | <.001 |
| Beta-blockers | 55.1% | 51.0% | <.001 |
| Anticoagulants | 13.4% | 10.4% | <.001 |
| Anesthesia | 82.7% | 92.3% | <.001 |

The unadjusted results to date from the TCAR Surveillance Project show that TCAR has provided similar in-hospital reduction in stroke risk as compared to CEA, despite treating sicker, older patients with TCAR, and TCAR showed significantly lower risk of cranial nerve injury. The incidence of in-hospital death in the unadjusted outcomes was slightly higher for TCAR due to the co-morbidities in the TCAR patients. Patients treated with TCAR were generally older and had more co-morbidities than the cohort of patients treated with CEA. As such, the odds ratio of in-hospital death between TCAR and CEA is the same when adjusting for patient risk factors.

In the unadjusted analysis, cranial nerve injury and bleeding were significantly different between TCAR and CEA. TCAR patients had a ten-fold reduction in risk of cranial nerve injury when compared to CEA, and TCAR had a significantly higher rate of bleeding. When adjusting for risk and in a propensity matched analysis, the rate of bleeding was not significantly different between TCAR and CEA, however, the significantly lower risk of cranial nerve injury with TCAR remained.

Average TCAR procedure time was significantly shorter and there was a significant reduction in the percent of hospital stays longer than one day, relative to CEA. These benefits can help hospitals to better utilize their operating room capacity and fixed overhead and reduce the number of procedures associated with hospital stays longer than one day, which have been shown to result in financial losses for the hospital facilities.

### *TCAR Surveillance Project: TCAR vs. CAS*

In a similar analysis comparing TCAR to CAS, TCAR showed significantly lower rates of stroke and death; stroke, death and myocardial infarction; in hospital death; and death within 30 days in both the adjusted and unadjusted analysis. When adjusted for baseline risk characteristics associated with the patient population, the difference in bleeding events was no longer significant. Below is a summary of the outcomes presented and patient demographics for patient characteristics with a statistically significant difference between the populations.

**TCAR vs. CAS Unadjusted Outcomes (in hospital)**

| Stroke and other adverse events | TCAR (%) N=2,545 | CAS (%) N=9,460 | P-Value |
|---|---|---|---|
| Stroke/Death | 1.8 | 3.3 | <.001 |
| Stroke/Death/Myocardial infarction | 2.1 | 3.5 | <.001 |
| Stroke | 1.4 | 2.2 | 0.02 |
| In-hospital Death | 0.5 | 1.4 | <.001 |
| 30-day Death | 0.9 | 2.0 | <.001 |
| Myocardial infarction | 0.4 | 0.3 | 0.62 |
| Bleeding | 1.4 | 0.6 | <.001 |

**TCAR vs CAS Baseline Demographics (% of patients)**

| | TCAR N=2,545 | CAS N=9,460 | P-Value |
|---|---|---|---|
| Age | 73.1 + 9.4 | 69.6 + 3.7 | <.001 |
| Black | 4.5% | 6.1% | <.01 |
| Asymptomatic | 52.3% | 38.1% | <.001 |
| Coronary artery disease | 51.3% | 38.9% | <.001 |
| Prior congestive heart failure | 18.8% | 16.6% | <.01 |
| Prior coronary artery bypass grafting | 23.7% | 20.8% | <.01 |
| Prior percutaneous coronary intervention | 28.2% | 25.7% | 0.01 |
| Chronic obstructive pulmonary disease | 29.2% | 27.0% | 0.03 |
| Glomerular filtration rate<60 | 40.6% | 34.5% | <.001 |
| Current Smoker | 23.5% | 28.5% | <.001 |
| Prior CEA | 25.1% | 28.2% | <.01 |
| Prior CAS | 8.0% | 19.3% | <.001 |
| Aspirin | 89.8% | 85.1% | <.001 |
| Antiplatelet (other than aspirin) | 84.7% | 74.7% | <.001 |
| Statin | 88.3% | 81.6% | <.001 |
| Beta-blockers | 55.1% | 52.6% | 0.03 |
| Anticoagulants | 13.4% | 11.7% | 0.02 |
| Medical high risk | 59.4% | 36.0% | <.001 |
| Anatomic high risk | 50.6% | 43.8% | <.001 |
| General Anesthesia | 82.7% | 20.0% | <.001 |

***Ongoing and Planned TCAR Studies***

In addition to the Society for Vascular Surgery's TCAR Surveillance Project and our ongoing ROADSTER 2 study, we have one ongoing study in the European Union enrolling up to 50 patients and evaluating the rate of sub-clinical embolization, or new white lesions, as detected on DW-MRI in recently symptomatic patients. Twenty-five patients have been enrolled to date at three hospitals in Germany, Belgium and Spain. The primary endpoint is the rate of ipsilateral new white lesions as seen on DW-MRI at 30 days compared to pre-procedure baseline white lesions. The evaluation of the presence of new white lesions is conducted in a blinded fashion by an independent neuroradiologist.

We are planning to conduct a similar study at four hospitals in the United States and one in the European Union. Institutional review board and ethics committee approvals are being sought and it is anticipated that enrollment will begin in the first quarter of 2019. Like the European Union study, the primary endpoint is the rate of ipsilateral new white lesions at 30 days. Enrollment of up to 75 patients is planned.

## Our Commercial Strategy

We designed our commercial strategy and built our direct sales force to target primarily vascular surgeons across the United States, who we believe represent the primary specialty managing the care of and receiving referrals for patients with carotid artery disease. We believe there are approximately 2,750 physicians, of which approximately 1,700 are vascular surgeons and 550 are cardiothoracic surgeons or neurosurgeons, and 750 hospitals that perform an estimated 80% of annual carotid revascularization procedures in the United States. Vascular surgeons are skilled in endovascular procedures and our sales, marketing, professional education and medical affairs efforts are focused on driving adoption and supporting their practice development by offering them an innovative, safe, effective and minimally-invasive alternative for treating carotid artery disease.

In the United States, we market and sell our portfolio of TCAR products for TCAR through a direct sales organization consisting of 27 sales representatives, known as area managers, or AM's, and 41 clinical support specialists, known as therapy development specialists, or TDS's, as of December 31, 2018. Our sales professionals have substantial experience launching and establishing new disruptive therapies and converting open surgical procedures to minimally-invasive alternatives. We primarily market our products directly to vascular surgeons, their staffs, operating room managers and hospital administrators. We also market to other specialists with experience in CEA and/or CAS with the appropriate skill set for TCAR, including neurosurgeons, cardiothoracic surgeons and non-surgical interventionalists in radiology, neuroradiology and cardiology. We do not currently sell our products in markets outside the United States.

Our area managers are responsible for developing territory business plans, targeting and opening new accounts, promoting the benefits of TCAR and our products, and driving adoption and penetration of TCAR. In addition, they help physicians and their staff to build TCAR programs, drive patient referral initiatives, and provide resources to help with practice development, reimbursement and patient education. Together with the therapy development specialists, they also support the training and proper use of our TCAR portfolio of products and provide clinically consultative support for patient selection, pre procedure planning, procedure support, and post-procedure care. As we continue to grow the size of our U.S. sales organization, with a focus on increasing adoption of TCAR by existing customers and expanding our current customer base, we expect to focus on adding a strategic mix of area managers and therapy development specialists.

Additionally, we support our sales organization with marketing and market and practice development initiatives. We plan to continue to expand and enhance our marketing and analytics capabilities to support our growing commercial organization and customer base.

***Professional Education and Sales Training***

We are focused on developing strong relationships with our customers and devote significant resources to training and educating physicians in the use of TCAR and our associated products. Our Office of Medical Affairs leads our physician education and training programs in addition to disseminating the scientific information and clinical data supporting TCAR. The Office of Medical Affairs also leads compliance activities.

Our practice is to require physicians to complete a training program before performing TCAR, which is also a regulatory requirement derived from the PMA approval of the ENROUTE stent. To facilitate training, we have developed a robust training course including clinical and procedural details as well as hands-on workshops designed to provide the highest potential for successful outcomes. We also selectively provide training through physician proctors on an as needed basis. Based on our experience, physicians usually require three to five procedures of dedicated training and achieve an adoption inflection point after approximately 10 procedures, after which point they require minimal ongoing case support from our sales team. As of December 31, 2018, we have trained approximately 775 physicians in the United States.

Through the Office of Medical Affairs, our highly specialized area managers and therapy development specialists, along with other key employees, receive in-depth training and develop a thorough understanding of carotid artery disease, patient selection, imaging interpretation, procedure planning, reimbursement and regulatory policies to meaningfully support our customers and maintain compliance. Our extensive training and continuous education program consists of in-person foundational training, procedure observation, and sales skills development. Our personnel are selected based on their focus on patient outcomes and the entire customer experience in addition to their technical aptitude.

## Coverage and Reimbursement

Since achieving regulatory clearances and approvals for our portfolio of TCAR products, we have successfully launched our products, driven adoption of TCAR and made significant progress securing reimbursement codes and payer coverage.

During the ROADSTER trial, the Society for Vascular Surgery helped to guide modifications of existing reimbursement coding descriptions to ensure their applicability to TCAR. In 2015, we also confirmed with CMS that TCAR, like CAS, was considered under the purview of the National Coverage Determination 20.7, or NCD, for Percutaneous Transluminal Angioplasty.

According to the Healthcare Utilization Project, Medicare is the primary payer for carotid revascularization procedures, representing approximately 78% of the payer mix for CEA and CAS procedures in 2014. TCAR is currently covered by CMS in high surgical risk patients who are symptomatic with greater than or equal to 70% stenosis. As of September 2016, TCAR is also covered by CMS in the TCAR Surveillance Project for high surgical risk patients who are either symptomatic with greater than or equal to 50% stenosis or asymptomatic with greater than or equal to 80% stenosis. We intend to seek FDA label expansion for our ENROUTE stent and CMS coverage for TCAR in standard surgical risk patients, as well as seek new and expanded coverage for TCAR in commercial payer coverage policies.

TCAR, like CAS, is only reimbursed by Medicare as an inpatient procedure and therefore reimbursed to hospitals under the DRG system.

There are three key aspects of reimbursement in the United States: coding, coverage and payment.

- ***Coding*** refers to distinct numeric and alphanumeric billing codes that are used by healthcare providers to report the provision of medical procedures and the use of supplies for specific patients to payers. CPT codes are published by the American Medical Association and are used to report medical services and procedures performed by or under the direction of physicians. Medicare pays physicians for services based on submission of a claim using one or more specific CPT codes. Physician payment for procedures may vary according to site of service. Hospitals are reimbursed for inpatient procedures based on Medicare Severity Diagnosis Related Group, or MS-DRG classifications derived from ICD-10-CM diagnosis and ICD-10-PCS codes that describe the patient's diagnoses and procedure(s) performed during the hospital stay. MS-DRGs closely calibrate payment for groups of services based on the severity of a patient's illness. One single MS-DRG payment is intended to cover all hospital costs associated with treating an individual during his or her hospital stay, with the exception of physician charges associated with performing medical procedures, which are reimbursed through CPT codes and payments.

- ***Payment*** refers to the amount paid to providers for specific procedures and supplies. Payment is generally determined by the specific billing code. In addition, there may be separate numeric codes, under which the billing code is classified, to establish a payment amount.

- ***Coverage*** refers to decisions made by individual payers as to whether or not to pay for a specific procedure and related supplies and if so, under what conditions, including specific diagnoses and clinical indications.

***Coding for Physicians***

In 2014, the Society for Vascular Surgery helped to guide an editorial change by the American Medical Association to CPT 37215 to be inclusive of TCAR. The Category I CPT code for TCAR, effective January 1, 2015, is CPT 37215: *Transcatheter placement of intravascular stent(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; with distal embolic protection*. Published CMS guidance confirms that reverse flow embolic protection systems, such as our ENROUTE NPS, qualify as distal embolic protection under this code. This code has a 90-day global period. Coverage and payment for CPT code 37215 is only available from CMS in the inpatient setting, subject to the terms of the National Coverage Determination Manual Section 20.7, and only available in facilities certified to have met CMS's minimum facility standards for performing carotid artery stenting, which include local credentialing requirements. Hospitals participating in the VQI are considered to meet CMS's minimum facility standards.

***Coding for Hospitals***

There are a number of appropriate ICD-10-CM diagnosis codes that describe occlusions and stenosis of carotid arteries for asymptomatic patients as well as cerebral infarction due to embolus and thrombus of carotid arteries for symptomatic patients. The proper ICD-10-PCS procedure codes for TCAR are 037H3DZ, 037J3DZ, 037K3DZ and 037L3DZ, and the appropriate MS-DRGs for TCAR are 034 when the patient presents with major complications or comorbidities, 035 when the patient presents with a complication or co-morbidity, and 036 for patients without complications or co-morbidities.

***Payment for Physicians***

The 2019 national average physician professional fee payment for CPT code 37215 will be approximately $1,050. We believe physicians feel this level of payment represents an attractive and reasonable amount for TCAR. CEA procedures are reimbursed under CPT code 35301, for which the 2019 national average physician professional fee payment will be $1,187.

***Payment for Hospitals***

The national unadjusted 2019 payment amounts for MS-DRGs 034, 035 and 036 are $21,992, $13,564 and $10,545 respectively. In 2019, the average payment amount across these three codes will be $13,132. These single MS-DRG payments are intended to cover all hospital costs associated with treating an individual during his or her hospital stay, with the exception of physician charges associated with performing medical procedures. We believe that facilities feel this level of payment represents a reasonable amount for the treatment of patients with carotid artery disease. CEA procedures are reimbursed under MS-DRGs 037, 038 and 039. In 2019, the national average payment amount across these three codes will be $9,048.

***Coverage***

According to the Healthcare Utilization Project, CMS was the primary payer for carotid procedures, covering 78% of CEA procedures and 77% of CAS procedures in 2014. In 2015, we also confirmed with CMS that TCAR, like CAS, was considered under the purview of the National Coverage Determination, or NCD, for Percutaneous Transluminal Angioplasty. Coverage of TCAR by Medicare, Medicaid, and private third-party payers is important for our commercial development. Currently, pursuant to the NCD for Percutaneous Transluminal Angioplasty, TCAR is covered by CMS under certain circumstances for high surgical risk patients; as well as certain other instances, including participation in certain trials and studies.

Patients at high risk for adverse events from CEA are defined as having significant comorbidities or anatomic risk factors and would be poor candidates for CEA. Symptoms of carotid artery stenosis include carotid transient ischemic attack, focal cerebral ischemia producing a nondisabling stroke, and transient monocular blindness. The determination that a patient is at high risk for adverse events from CEA and the patient's symptoms arising from carotid artery stenosis must be documented in the patient's medical records.

CMS has created a list of minimum standards modeled in part on professional society statements on competency. All facilities must at least meet CMS standards in order to receive coverage for CAS, inclusive of TCAR, for high surgical risk patients. Participation in the Society for Vascular Surgery's Vascular Quality Initiative can provide evidence of compliance to these standards to CMS.

The TCAR Surveillance Project is an FDA-approved extension study. We understand that Medicare has reimbursed hospitals and physicians for symptomatic patients with greater than or equal to 50% carotid artery stenosis and asymptomatic high surgical risk patients with greater than or equal to 80% carotid artery stenosis who participate in the TCAR Surveillance Project. For billing purposes, facilities and providers can submit claims for the TCAR Surveillance Project using National Clinical Trial identifier NCT02850588.

ROADSTER 2 is another FDA-approved Post Approval Study. We believe that patients who meet the inclusion/exclusion criteria for ROADSTER 2 may be eligible for CMS coverage under the NCD under certain circumstances. Symptomatic patients with greater than or equal to 50% carotid artery stenosis and asymptomatic high surgical risk patients with greater than or equal to 80% carotid artery stenosis may be eligible. Providers must bill the Pre-Market Approval number assigned to the stent system by the FDA, P140026, to obtain reimbursement.

The ENROUTE NPS and the ENROUTE stent are also included in the CREST-2 Companion Registry, or C2R, but not in the CREST 2 randomized clinical trial itself. The objective of C2R is to promote the rapid initiation and completion of enrollment in the CREST-2 randomized clinical trial (clinicaltrials.gov ID NCT02089217). Patient eligibility will include standard surgical risk and high surgical risk patients with symptomatic or asymptomatic carotid artery disease. Patients will be followed for the occurrence of post-procedural complications. The primary safety and quality endpoint for C2R is the

occurrence of any stroke or death within the 30-day period following the stenting procedure. The safety and quality results from C2R will guide selection of interventionists for participation in the CREST-2 randomized clinical trial. Enrollment into C2R began in 2015 and will continue until publication of the primary results of the randomized trial. Providers can bill CMS for TCAR patients enrolled in this registry using NCT02240862.

## Research, Development and Clinical Programs

Our research and development activities encompass basic research, clinical research and product development. Our engineering team has mechanical engineering, project management, materials science, and prototyping expertise. In addition, our clinical research organization has trial design and management, data collection and biostatistics expertise.

Our research and development efforts are currently focused on improving and expanding our portfolio of TCAR products and their labeled indications for use to further improve and simplify the treatment experience for a broad base of patients and physicians. We have worked together with vascular surgeons such as Enrique Criado M.D., and David Chang M.D., the pioneers of TCAR, to develop our products. We believe our research and development capabilities, clinical and regulatory organizations and unique insights will enable us to continue to lead this emerging category.

Our current clinical program consists of support for our ongoing ROADSTER 2 U.S. Post-Market approval study to evaluate TCAR outcomes in broader, “real world” use. We are also enrolling and planning studies in the European Union and United States, respectively, to evaluate the rate of sub-clinical embolization as detected through DW-MRI in recently symptomatic patients. We expect to utilize the results of these clinical studies to support our marketing efforts and encourage continued adoption of TCAR.

We also have a broad intellectual property platform addressing the transcarotid approach and, in the future, we intend to leverage our expertise to develop new products targeting market opportunities and disease states that could benefit from the physiologic and engineering advantages made possible by our transcarotid approach, including in the heart, aortic arch and brain.

For the fiscal years ended December 31, 2017 and 2018, our research, development and clinical expenses were $7.2 million and $10.3 million, respectively.

## Competition

TCAR is a relatively new procedure category and as such the basis of competition for our products is with respect to alternative carotid revascularization procedures. We are positioning TCAR as an alternative to the existing procedures CEA and CAS, and therefore compete primarily with manufacturers of medical devices used in those procedures.

The major manufacturers of products, such as patches and shunts, used in connection with CEA include LeMaitre Vascular, Getinge / Maquet, Baxter, Terumo, Gore and Edwards. Many of these companies are large public companies or divisions of publicly-traded companies and have several competitive advantages, including established relationships with vascular surgeons who commonly perform the CEA procedure, significantly greater name recognition and significantly greater sales and marketing resources.

Companies with actively marketed FDA-approved stents and embolic protection devices for use with CAS procedures include Abbott, Medtronic, Boston Scientific, and Cardinal. Other companies have approved devices not currently marketed in the United States, including Gore and InspireMD. Additionally, some companies have stents and other products under development for use in CAS procedures, including Terumo. Most of these companies have several competitive advantages including

the following: more established sales and marketing programs and networks, larger portfolio of products, longer operating histories, established relationships with healthcare professionals and greater name recognition.

In addition to competing for market share for TCAR, we also compete against these companies for personnel, including qualified personnel that are necessary to grow our business.

We believe the principal competitive factors in our market include the following:

- Patient outcomes and adverse event rates;
- Patient experience;
- Acceptance by treating physicians and referral sources;
- Physician learning curve;
- Ease-of-use and reliability;
- Patient recovery time and level of discomfort;
- Economic benefits and cost savings;
- Availability of reimbursement; and
- Strength of clinical evidence.

We also compete against manufacturers of medications used for medical management of carotid artery disease, including aspirin and statins. Many such companies are large public companies or divisions of publicly-traded companies and have several competitive advantages including the following: established treatment patterns where drugs are generally first-line therapy and invasive procedures or surgery are considered later; established relationships with general practitioners who commonly prescribe such medications; significantly greater name recognition; and significantly greater sales and marketing resources, including direct-to-consumer advertising.

Finally, we may compete with medical device and pharmaceutical manufacturers outside the United States when we pursue plans to market our products internationally. Among other competitive advantages, such companies may have more established sales and marketing programs and networks, established relationships with healthcare professionals and greater name recognition in such markets.

## Intellectual Property

We actively seek to protect the intellectual property and proprietary technology that we believe is important to our business, which includes seeking and maintaining patents covering our technology and products, proprietary processes and any other inventions that are commercially or strategically important to the development of our business. We also rely upon trademarks to build and maintain the integrity of our brand, and we seek to protect the confidentiality of trade secrets that may be important to the development of our business.

To protect our proprietary rights, we rely on a combination of trademark, copyright, patent, trade secret and other intellectual property laws, employment, confidentiality and invention assignment agreements, and protective contractual provisions with our employees, contractors, consultants, suppliers, partners and other third parties.

As of December 31, 2018, we owned 47 patents globally, of which 34 were issued U.S. patents and 13 were patents outside of the United States. As of December 31, 2018, we had 40 pending patent

applications globally, including 20 in the United States and 20 outside the United States. Our patents expire between November 2024 and November 2034. Our material patents, their jurisdiction, expiration date and the product to which they relate, are listed in the table below:

| Jurisdiction | Patent No. | Expiration Date | Related Product |
|---|---|---|---|
| US | 8,002,728 | 12/2/2025 | Transcarotid Neuroprotection System |
| US | 8,343,089 | 6/22/2025 | Transcarotid Neuroprotection System<br>Transcarotid Stent System |
| US | 8,157,760 | 9/3/2030 | Transcarotid Neuroprotection System |
| US | 8,784,355 | 8/7/2029 | Transcarotid Neuroprotection System |
| US | 8,740,834 | 3/6/2029 | Transcarotid Neuroprotection System |
| US | 9,011,364 | 4/10/2031 | Transcarotid Neuroprotection System |
| US | 9,833,555 | 10/26/2029 | Transcarotid Neuroprotection System |
| Europe | 2,173,425 | 7/18/2028 | Transcarotid Neuroprotection System |
| France | 2,173,425 | 7/18/2028 | Transcarotid Neuroprotection System |
| Germany | 2,173,425 | 7/18/2028 | Transcarotid Neuroprotection System |
| Italy | 2,173,425 | 7/18/2028 | Transcarotid Neuroprotection System |
| Great Britain | 2,173,425 | 7/18/2028 | Transcarotid Neuroprotection System |
| Japan | 5,290,290 | 7/18/2028 | Transcarotid Neuroprotection System |
| Japan | 5,693,661 | 7/18/2028 | Transcarotid Neuroprotection System |

As of December 31, 2018, we had trademark registrations for “Silk Road Medical,” the “Silk Road Medical” logo, “Enroute” and the “Enroute” logo and "Enhance" in the United States, and various other countries. Including these trademark registrations, our trademark portfolio contained 13 trademark registrations, six of which were U.S. trademark registrations and three pending trademark applications in United States and various other countries.

The term of individual patents depends on the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a nonprovisional patent application in the applicable country. We cannot assure that patents will be issued from any of our pending applications or that, if patents are issued, they will be of sufficient scope or strength to provide meaningful protection for our technology. Notwithstanding

the scope of the patent protection available to us, a competitor could develop treatment methods or devices that are not covered by our patents. Furthermore, numerous U.S. and foreign-issued patents and patent applications owned by third parties exist in the fields in which we are developing products. Because patent applications can take many years to issue, there may be applications unknown to us, which applications may later result in issued patents that our existing or future products or technologies may be alleged to infringe.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. In the future, we may need to engage in litigation to enforce patents issued or licensed to us, to protect our trade secrets or know-how, to defend against claims of infringement of the rights of others or to determine the scope and validity of the proprietary rights of others. Litigation could be costly and could divert our attention from other functions and responsibilities. Furthermore, even if our patents are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market."

Adverse determinations in litigation could subject us to significant liabilities to third parties, could require us to seek licenses from third parties and could prevent us from manufacturing, selling or using the product, any of which could severely harm our business.

We also seek to maintain certain intellectual property and proprietary know-how as trade secrets, and generally require our partners to execute non-disclosure agreements prior to any substantive discussions or disclosures of our technology or business plans. Our trade secrets include proprietary account analytics, user training methods, and operational processes. For more information, please see "Risk Factors—Risks Related to Intellectual Property."

## Manufacturing and Supply

We currently manufacture the ENROUTE NPS at and distribute all of our products from our approximately 31,000 square foot facility in Sunnyvale, California. This facility provides approximately 8,000 square feet of space for our production and distribution operations, including manufacturing, quality control and storage. We believe our existing facility will be sufficient to meet our manufacturing needs for at least the next four years.

Our manufacturing and distribution operations are subject to regulatory requirements of the FDA's Quality System Regulation, or QSR, for medical devices sold in the United States, set forth in 21 CFR part 820, and the European Medical Device Directive 93/42/EEC and amendments, or MDD, for medical devices marketed in the European Union. We are also subject to applicable local regulations relating to the environment, waste management and health and safety matters, including measures relating to the release, use, storage, treatment, transportation, discharge, disposal, sale, labeling, collection, recycling, treatment and remediation of hazardous substances.

The FDA monitors compliance with the QSR through periodic inspections of our facilities and may include our suppliers' facilities as well. Our European Union Notified Body, British Standards Institute, or BSI, monitors compliance with the MDD requirements through both annual scheduled audits and periodic unannounced audits of our manufacturing facilities as well as our contract manufacturers' facilities.

Our failure, or the failure of our suppliers, to maintain acceptable quality requirements could result in the shutdown of our manufacturing operations or the recall of our products, which would harm our business. In the event that one of our suppliers fails to maintain acceptable quality requirements, we may have to qualify a new supplier and could experience a material adverse effect to manufacturing and manufacturing delays as a result.

Our quality management system is ISO 13485 and MDD Certified. We have been an FDA registered medical device establishment and California licensed medical device manufacturer since 2011. We moved to our current Sunnyvale, California facility in June 2018, which was registered with the FDA in June 2018 and was issued a California device manufacturing license in August 2018. An ISO 13485 audit was conducted in September 2018 and our facility was recommended for certification.

The FDA conducted a total of four establishment inspections of our manufacturing facility in Sunnyvale, California in 2014, 2015 and 2016. A single Form 483 Notice of Observation was issued in April 2015 relating to a transcription error in patient line listings and no additional follow up with the FDA was required. We believe that we are in compliance, in all material respects, with all applicable FDA and QSR requirements.

Since obtaining ISO 13485 certification in 2011, BSI has conducted scheduled surveillance audits annually, recertification audits every third year, and unannounced audits once during every three-year certification period starting in 2011 for compliance with ISO 13485 and MDD. The most recent recertification audit was conducted in September 2017, and no major non-conformities were identified. The most recent surveillance audit was conducted in September 2018, and no major non-conformities were identified. The most recent unannounced audit was conducted in July 2014, and no major non-conformities were identified. We believe that we are in compliance, in all material respects, with all ISO 13485 and MDD requirements.

Manufacturing of the materials and components of the ENROUTE NPS are provided by approved suppliers, all of which are single source suppliers of key components, sub-assemblies and materials. We purchase finished transcarotid access kit, guidewires and stents through contract manufacturers. Cardinal is our contract manufacturer and currently the sole source supplier for the ENROUTE stent. We typically maintain several months' worth of ENROUTE stents in inventory, and we estimate that it would take between one and two years to qualify a second source supplier for our ENROUTE stent. The suppliers for the ENROUTE NPS and our other product lines are evaluated, qualified and approved through a stringent supplier management program, which includes various evaluations, assessments, qualifications, validations, testing and inspection to ensure the supplier can meet acceptable quality requirements. We implement a strict change control policy with our key suppliers to ensure that no component or process changes are made without our prior approval.

Order quantities and lead times for components purchased from suppliers are based on our forecasts derived from historical demand and anticipated future demand. Lead times for components may vary depending on the size of the order, time required to fabricate and test the components, specific supplier requirements and current market demand for the components, sub-assemblies and materials. We perform assembly, testing, inspection and final product release activities for the ENROUTE NPS. Finished ENROUTE NPS devices are ethylene oxide sterilized at a qualified supplier.

## Government Regulation

***United States Food & Drug Administration***

Our products and operations are subject to extensive and ongoing regulation by the FDA under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations, as well as other federal and state regulatory bodies in the United States. The laws and regulations govern, among other things, product design and development, pre-clinical and clinical testing, manufacturing, packaging, labeling, storage, record keeping and reporting, clearance or approval, marketing, distribution, promotion, import and export, and post-marketing surveillance.

Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the Federal Food, Drug and

Cosmetic Act, or FDCA, also referred to as a 510(k) clearance, or approval from the FDA of a PMA application. Both the 510(k) clearance and PMA processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees, unless an exemption is available.

***Device classification***

Under the FDCA, medical devices are classified into one of three classes-Class I, Class II or Class III-depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to a set of FDA regulations, referred to as the General Controls for Medical Devices, which require compliance with the applicable portions of the QSR, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices, also called Class I reserved devices, also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, patient registries, FDA guidance documents and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA application process, which is generally more costly and time consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

***The investigational device process***

In the United States, absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval require an IDE application. Some types of studies deemed to present "non-significant risk" are deemed to have an approved IDE once certain requirements are addressed and IRB approval is obtained. If the device presents a "significant risk" to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate institutional review boards at the clinical trial sites. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials, and although the FDA's approval

of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and effectiveness, even if the trial meets its intended success criteria.

All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's good clinical practice regulations for institutional review board approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable, or, even if the intended safety and effectiveness success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application, for numerous reasons, including, but not limited to, the following:

- The FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- Patients do not enroll in clinical trials at the rate expected;
- Patients do not comply with trial protocols;
- Patient follow-up is not at the rate expected;
- Patients experience adverse events;
- Patients die during a clinical trial, even though their death may not be related to the products that are part of the trial;
- Device malfunctions occur with unexpected frequency or potential adverse consequences;
- Side effects or device malfunctions of similar products already in the market that change the FDA's view toward approval of new or similar PMAs or result in the imposition of new requirements or testing;
- Institutional review boards and third-party clinical investigators may delay or reject the trial protocol;
- Third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, investigator agreement, investigational plan, good clinical practices, the IDE regulations, or other FDA or IRB requirements;
- Third-party investigators are disqualified by the FDA;
- We or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans, or otherwise fail to comply with the IDE regulations governing responsibilities, records, and reports of sponsors of clinical investigations;
- Third-party clinical investigators have significant financial interests related to us or our study such that the FDA deems the study results unreliable, or the company or investigators fail to disclose such interests;
- Regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;

- Changes in government regulations or administrative actions;
- The interim or final results of the clinical trial are inconclusive or unfavorable as to safety or effectiveness; or
- The FDA concludes that our trial design is unreliable or inadequate to demonstrate safety and effectiveness.

***The 510(k) approval process***

Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent," as defined in the statute, to a legally marketed predicate device.

A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was previously found substantially equivalent through the 510(k) process. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence.

After a 510(k) premarket notification is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the de novo process. A manufacturer can also submit a petition for direct de novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510 (k) clearance or, depending on the modification, could require a PMA application or de novo classification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications are accomplished by a letter-to-file in which the manufacture documents the change in an internal letter-to-file. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained.

***The PMA approval process***

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA, by statute and by regulation, has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA. The FDA considers a PMA or PMA supplement to have been voluntarily withdrawn if an applicant fails to respond to an FDA request for information (e.g., major deficiency letter) within a total of 360 days. Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years, but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- The device may not be shown safe or effective to the FDA's satisfaction;
- The data from pre-clinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- The manufacturing process or facilities may not meet applicable requirements; and
- Changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements are required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer term safety and effectiveness data for the device. The FDA may also require post-market surveillance for certain devices cleared under a 510(k) notification, such as implants or life-supporting or life-sustaining devices used outside a device user facility. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use.

***Pervasive and Continuing Regulation***

After a device is placed on the market, numerous regulatory requirements continue to apply. These include:

- The FDA's QSR, which requires manufacturers, including their suppliers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- Labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;
- Medical device reporting, or MDR, regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- Medical device recalls, which require that manufacturers report to the FDA any recall of a medical device, provided the recall was initiated to either reduce a risk to health posed by the device, or to remedy a violation of the FDCA caused by the device that may present a risk to health; and
- Post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Public Health, or CDPH. The FDA and CDPH have broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDPH to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. Additionally, our Notified Body, the British Standards Institution, or BSI, regularly inspects our manufacturing, design and operational facilities to ensure ongoing ISO 13485 compliance in order to maintain our CE mark.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- Warning letters, fines, injunctions, consent decrees and civil penalties;
- Repair, replacement, refunds, recall or seizure of our products;
- Operating restrictions, partial suspension or total shutdown of production;
- Refusing our requests for 510 (k) clearance or premarket approval of new products, new intended uses or modifications to existing products;

- Withdrawing 510 (k) clearance or premarket approvals that have already been granted; and
- Criminal prosecution.

***European Union***

Our portfolio of TCAR products is regulated in the European Union as a medical device per the European Union Directive 93/42/EEC, also known as the Medical Device Directive, or MDD. The MDD sets out the basic regulatory framework for medical devices in the European Union. The system of regulating medical devices operates by way of a certification for each medical device. Each certified device is marked with the CE mark which shows that the device has a Certificat de Conformité. There are national bodies known as Competent Authorities in each member state which oversee the implementation of the MDD within their jurisdiction. The means for achieving the requirements for the CE mark vary according to the nature of the device. Devices are classified in accordance with their perceived risks, similarly to the U.S. system. The class of a product determines the conformity assessment required before the CE mark can be placed on a product. Conformity assessments for our products are carried out as required by the MDD. Each member state can appoint Notified Bodies within its jurisdiction. If a Notified Body of one member state has issued a Certificat de Conformité, the device can be sold throughout the European Union without further conformance tests being required in other member states. The CE mark is contingent upon continued compliance with the applicable regulations and the quality system requirements of the ISO 13485 standard. Our current CE mark is issued by BSI.

***Health Insurance Portability and Accountability Act***

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, established federal protection for the privacy and security of health information. Under HIPAA, the Department of Health and Human Services, or HHS, has issued regulations to protect the privacy and security of protected health information used or disclosed by "Covered Entities," including healthcare providers and their Business Associates. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for health plans and providers. The privacy regulations protect medical records and other protected health information by limiting their use and release, giving patients the right to access their medical records and limiting most disclosures of health information to the minimum amount necessary to accomplish an intended purpose. The HIPAA security standards require the adoption of administrative, physical, and technical safeguards and the adoption of written security policies and procedures. HIPAA requires Covered Entities to execute Business Associate Agreements with their Business Associates and subcontractors, who provide services to Covered Entities and who need access to protected health information. In addition, companies that would not otherwise be subject to HIPAA may become contractually obligated to follow HIPAA requirements through agreements with Covered Entities and Business Associates, and some of our customers may require us to agree to these provisions.

In addition HIPAA and other federal privacy regulations, such as Section 5 of the Federal Trade Commission Act, there are a number of state laws regarding the privacy and security of health information and personal data that apply to us. The compliance requirements of these laws, including additional breach reporting requirements, and the penalties for violation vary widely, and new privacy and security laws in this area are evolving. Requirements of these laws and penalties for violations vary widely.

If we or our operations are found to be in violation of HIPAA, HITECH, or their implementing regulations, we may be subject to penalties, including civil and criminal penalties, fines, and exclusion from participation in federal or state healthcare programs, and the curtailment or restructuring of our operations. HITECH increased the civil and criminal penalties that may be imposed against Covered Entities, their Business Associates and possibly other persons, and gave state attorneys general new

authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

***U.S. Federal, State and Foreign Fraud and Abuse Laws***

The federal and state governments have enacted, and actively enforce, a number of laws to address fraud and abuse in federal healthcare programs. Our business is subject to compliance with these laws.

***Anti-Kickback Statutes***

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

The definition of "remuneration" has been broadly interpreted to include anything of value, including, for example, gifts, certain discounts, the furnishing of free supplies, equipment or services, credit arrangements, payment of cash and waivers of payments. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered businesses, the statute has been violated. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $100,000 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines of up to $100,000 and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid. In addition some kickback allegations have been claimed to violate the Federal False Claims Act.

The Office of Inspector General, or OIG, of the HHS has issued a series of regulations known as "safe harbors." These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy an applicable safe harbor may result in increased scrutiny by government enforcement authorities such as OIG.

Many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to referral of recipients for healthcare products or services reimbursed by any source, not only government healthcare programs, and may apply to payments made directly by the patient.

Government officials have focused their enforcement efforts on the marketing of healthcare services and products, among other activities, and recently have brought cases against companies, and certain individual sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

***Federal False Claims Act***

The federal False Claims Act, or FCA, imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The *qui tam* provisions of the FCA allow a private individual to bring actions on behalf of the federal government alleging that the defendant has violated the FCA and to share in any monetary recovery. In addition, various states have enacted false claims laws analogous to the FCA, and many of these state laws apply where a claim is submitted to any third-party payer and not only a federal healthcare program.

When an entity is determined to have violated the FCA, it may be required to pay up to three times the actual damages sustained by the government, plus civil fines and penalties ranging from $11,181 and $22,363 for each false claim. As part of any settlement, the government may require the entity to enter into a corporate integrity agreement, which imposes certain compliance, certification and reporting obligations. There are many potential bases for liability under the FCA. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The federal government has used the FCA to assert liability on the basis of kickbacks, or in instances in which manufacturers have provided billing or coding advice to providers that the government considered to be inaccurate. In these cases, the manufacturer faces liability for "causing" a false claim. In addition, the federal government has prosecuted companies under the FCA in connection with off-label promotion of products. Our activities relating to the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products and the sale and marketing of our products may be subject to scrutiny under these laws.

While we are unaware of any current matters, we are unable to predict whether we will be subject to actions under the FCA or a similar state law, or the impact of such actions. However, the costs of defending such claims, as well as any sanctions imposed, could significantly affect our financial performance.

***Civil Monetary Penalties***

The Civil Monetary Penalty Act of 1981 imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier.

***Open Payments***

The Physician Payment Sunshine Act, known as "Open Payments" and enacted as part of the Affordable Care Act, requires all pharmaceutical and medical device manufacturers of products covered by Medicare, Medicaid or the Children's Health Insurance Program to report annually to HHS: payments and transfers of value to physicians, certain other healthcare providers, and teaching hospitals, and applicable manufacturers and group purchasing organizations, to report annually ownership and investment interests held by physicians and their immediate family members. Applicable manufacturers are required to submit annual reports to CMS. Failure to submit required information may result in civil monetary penalties of $11,052 per failure up to an aggregate of $165,786 per year (or up to an aggregate of $1.105 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations. We are subject to Open Payments and the information we disclose may lead to greater scrutiny, which may result in modifications to established practices and additional costs. Additionally, similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with healthcare professionals.

***Foreign Corrupt Practices Act***

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation,

including international subsidiaries, if any, and to devise and maintain an adequate system of internal accounting controls for international operations.

***International Laws***

In Europe, various countries have adopted anti-bribery laws providing for severe consequences in the form of criminal penalties and significant fines for individuals or companies committing a bribery offense. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation.

For instance, in the United Kingdom, under the U.K. Bribery Act 2010, a bribery occurs when a person offers, gives or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the U.K. Bribery Act 2010. An individual found in violation of the U.K. Bribery Act 2010, faces imprisonment of up to ten years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

There are also international privacy laws that impose restrictions on the access, use, and disclosure of health information. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain required patient information could significantly impact our business and our future business plans.

***U.S. Centers for Medicare and Medicaid Services***

Medicare is a federal program administered by CMS through fiscal intermediaries and carriers. Available to individuals age 65 or over, and certain other individuals, the Medicare program provides, among other things, healthcare benefits that cover, within prescribed limits, the major costs of most medically necessary care for such individuals, subject to certain deductibles and copayments.

CMS has established guidelines for the coverage and reimbursement of certain products and procedures by Medicare. In general, in order to be reimbursed by Medicare, a healthcare procedure furnished to a Medicare beneficiary must be reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body part. The methodology for determining coverage status and the amount of Medicare reimbursement varies based upon, among other factors, the setting in which a Medicare beneficiary received healthcare products and services. Any changes in federal legislation, regulations and policy affecting CMS coverage and reimbursement relative to the procedure using our products could have a material effect on our performance.

CMS also administers the Medicaid program, a cooperative federal/state program that provides medical assistance benefits to qualifying low income and medically needy persons. State participation in Medicaid is optional, and each state is given discretion in developing and administering its own Medicaid program, subject to certain federal requirements pertaining to payment levels, eligibility criteria and minimum categories of services. The coverage, method and level of reimbursement vary from state to state and is subject to each state's budget restraints. Changes to the availability of coverage, method or level of reimbursement for TCAR may affect future revenue negatively if reimbursement amounts are decreased or discontinued.

All CMS programs are subject to statutory and regulatory changes, retroactive and prospective rate adjustments, administrative rulings, interpretations of policy, intermediary determinations, and government funding restrictions, all of which may materially increase or decrease the rate of program payments to healthcare facilities and other healthcare providers, including those paid for TCAR.

***United States Health Reform***

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions. Changes in healthcare policy could increase our costs, decrease our revenue and impact sales of and reimbursement for our current and future products. The ACA substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts our industry. The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payers and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

The implementation of the Affordable Care Act in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The Affordable Care Act imposed, among other things, a 2.3% federal excise tax, with limited exceptions, on any entity that manufactures or imports Class I, II and III medical devices offered for sale in the United States that began on January 1, 2013. Through a series of legislative amendments, the tax was suspended for 2016 through 2019. Absent further legislative action, the device excise tax will be reinstated on medical device sales starting January 1, 2020. The Affordable Care Act also provided incentives to programs that increase the federal government's comparative effectiveness research, and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Additionally, the Affordable Care Act has expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. We do not yet know the full impact that the Affordable Care Act will have on our business. There have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect additional challenges and amendments in the future. Moreover, the Trump Administration and the U.S. Congress may take further action regarding the Affordable Care Act, including, but not limited to, repeal or replacement. Most recently, the Tax Cuts and Jobs Acts was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance, beginning in 2019.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to CMS payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced CMS payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We believe that there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payers to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our current and future products from governmental agencies or third-party payers. Current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

## Employees

As of December 31, 2018, we had 176 full-time employees. We believe that the success of our business will depend, in part, on our ability to attract and retain qualified personnel. None of our employees are represented by a labor union or are a party to a collective bargaining agreement and we believe that our employee relations are good.

## Facilities

We currently lease approximately 31,000 square feet for our corporate headquarters and manufacturing facility located in Sunnyvale, California under a lease agreement which terminates in 2024. We believe that this facility is sufficient to meet our current and anticipated needs in the near term and that additional space can be obtained on commercially reasonable terms as needed.

## Legal Proceedings

From time to time we may become involved in legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business.

In February 2019, a former employee, through counsel, advised us that he had filed a charge of discrimination against us with the California Department of Fair Employment & Housing, or DFEH. The former employee's complaint alleges sexual harassment and retaliation in violation of the California Department of Fair Employment & Housing Act. The complaint does not allege specific damages. To date, the DFEH has not contacted us. We deny the complaint's allegations and intend to vigorously defend ourselves. We have tendered the claim to our insurance carrier, and the carrier has appointed a law firm to represent us in this matter.

# MANAGEMENT

## Executive Officers and Directors

The following table sets forth information, as of December 31, 2018, regarding our executive officers and directors.

| Name | Age | Title |
|---|---|---|
| **Executive Officers** | | |
| Erica J. Rogers | 55 | President, Chief Executive Officer and Director |
| Lucas W. Buchanan | 41 | Chief Financial Officer |
| Andrew S. Davis | 50 | Executive Vice President of Global Sales and Marketing |
| **Non-Employee Directors** | | |
| Ruoxi Chen[(1)(2)] | 35 | Director |
| Tony M. Chou, M.D. | 58 | Director |
| Jack W. Lasersohn[(2)] | 65 | Director |
| Robert E. Mittendorff, M.D.[(2)] | 42 | Director |
| Amr Kronfol | 38 | Director |
| Elizabeth H. Weatherman[(1)] | 58 | Director |
| Donald J. Zurbay[(1)] | 51 | Director |

(1) Member of the audit committee.
(2) Member of the compensation committee.

## Executive Officers

***Erica J. Rogers.*** Ms. Rogers has served as our President and Chief Executive Officer and a member of our board of directors since October 2012. Ms. Rogers previously served as Chief Operating Officer of Medicines360, a non-profit pharmaceutical company developing drugs and devices for women from June 2010 to October 2012. Ms. Rogers was an Executive Vice President at Nanosys, Inc. from December 2008 to March 2010. Prior to that, Ms. Rogers founded and was Chief Executive Officer of Allux Medical, and co-founded Visiogen, which was acquired by Abbott Medical Optics in 2009. She worked previously in neurovascular marketing at Target Therapeutics and peripheral vascular sales and sales training at Boston Scientific. Ms. Rogers received a B.S. in zoology from San Diego State University.

We believe Ms. Rogers' management experience in the medical device industry, her experience in founding and building medical device companies and her extensive understanding of our business, operations, and strategy qualify her to serve on our board of directors.

***Lucas W. Buchanan.*** Mr. Buchanan has served as our Chief Financial Officer since July 2016 and since August 2009 has held multiple roles including Executive Vice President, Commercialization and Corporate Development and Vice President, Marketing and Business Development. From May 2013 to May 2014, Mr. Buchanan was a Senior Director of Strategy and Corporate Development at Impax Laboratories. From 2009 to 2011, Mr. Buchanan was part of our early team while employed at The Vertical Group, a venture capital firm and the founder of our company. He previously worked at Medtronic and at Ernst & Young Corporate Finance LLC. Mr. Buchanan received a B.A. in economics from Duke University and an M.B.A. in health care management from The Wharton School at the University of Pennsylvania.

***Andrew S. Davis***. Mr. Davis joined us in May 2015 as our Executive Vice President of Global Sales and Marketing. From September 2014 to May 2015, Mr. Davis was Vice President of Sales and Marketing for U.S. and Canada in the Advanced Wound Therapy Group of Acelity. Mr. Davis previously held various leadership positions at Medtronic from 1999 until September 2014, where he most recently served as U.S. Vice President of Sales for CoreValve catheter-based therapies and prior to that U.S. Vice President of Sales for Endovascular. Prior to Medtronic, Mr. Davis worked in sales at Boston Scientific. Mr. Davis received a B.S. in political science from Florida State University.

## Non-Employee Directors

***Ruoxi Chen***. Mr. Chen has served as a member of our board of directors since August 2016. Since August 2011 Mr. Chen has been employed at Warburg Pincus, where he is currently a Principal, focusing on healthcare and consumer investments. Mr. Chen previously worked as an Associate at The Carlyle Group from 2007 to 2009 and in investment banking at Citigroup Global Markets from 2005 to 2007. Mr. Chen received a B.S. in economics and computer science from Duke University and an M.B.A. from Harvard Business School.

We believe Mr. Chen is qualified to serve on our board of directors due to his extensive experience as a private equity investor in healthcare and medical device companies.

***Tony M. Chou, M.D.*** Dr. Chou has served as a member of our board of directors since March 2007. Dr. Chou has been a general partner at The Vertical Group, a healthcare-focused venture capital firm, since August 2006. After joining The Vertical Group, Dr. Chou co-founded our company in 2007 and served as Chief Executive Officer until November 2010. Prior to that, Dr. Chou had general management and business development responsibilities in the Abbott Vascular Division of Abbott Laboratories and last served as Division Vice President and General Manager of vascular closure, managing the FDA approval and global launch of the Perclose and Starclose products. Dr. Chou was previously the Director of the Adult Cardiac Catheterization Laboratory at the University of California, San Francisco, where he is currently Associate Professor of Medicine. Dr. Chou received a B.S. in physics and electrical engineering from Carnegie Mellon University and an M.D. from Case Western Reserve University.

We believe Dr. Chou is qualified to serve on our board of directors due to his role as a co-founder of our company, background as a practicing physician and professor of medicine, experience in the medical device industry and extensive knowledge of our business.

***Jack W. Lasersohn, J.D.*** Mr. Lasersohn has served as a member of our Board since April 2007. Since 1988, Mr. Lasersohn has been a general partner, or a principal of the general partner, of The Vertical Group, L.P., a private venture capital firm that is focused on the fields of medical technology and biotechnology. The Vertical Group was a co-founder of our company. Prior to joining The Vertical Group's predecessor, F. Eberstadt, in 1981, Mr. Lasersohn was a corporate attorney with Cravath, Swaine & Moore LLP. Mr. Lasersohn served on the board of directors of Masimo Corporation, a publicly traded global medical technology company, from January 1995 to 2017 and has served on the board of directors of OncoMed Pharmaceuticals, Inc., a publicly traded clinical development-stage biopharmaceutical company, since July 2005. He also serves on the boards of a number of private medical device and biotechnology companies. Mr. Lasersohn is the past Chairman of the Medical Industry Group of the National Venture Capital Association, or NVCA, and previously served on the Executive Committee of the board of directors of the NVCA. Mr. Lasersohn has also served, by appointment, on various committees advising the U.S. Food and Drug Administration and the Center for Medicare and Medicaid Services. He holds a B.S. in physics from Tufts University, an M.A. from The Fletcher School of Law and Diplomacy, and a J.D. from Yale Law School.

We believe Mr. Lasersohn is qualified to serve on our board of directors due to his extensive experience as a venture capital investor and as a member of the boards of directors of multiple public and private medical device and biotechnology companies.

***Robert E. Mittendorff, M.D.*** Dr. Mittendorff has served on our board of directors since July 2017. Dr. Mittendorff has been a partner at Norwest Venture Partners since February 2012. Dr. Mittendorff was previously the VP of Marketing and Business Development at Hansen Medical, Inc. Dr. Mittendorff currently serves on the board of directors of several private companies and is also a board certified emergency physician. Dr. Mittendorff received a B.S. in biomedical engineering from Johns Hopkins University, an M.D. from Harvard Medical School and an M.B.A. from Harvard Business School.

We believe Dr. Mittendorff is qualified to serve on our board of directors due to his background as a practicing physician, extensive experience as an investor and his role as a board member of several medical device companies.

***Amr Kronfol***. Mr. Kronfol has served on our board of directors since March 2019. Mr. Kronfol has been employed at Warburg Pincus since 2009, where he has been a Managing Director since 2018, focusing on investment activities in the healthcare, technology and consumer/retail industries. He previously worked at Merrill Lynch, where he was a Vice President in the fixed income division and at Tigris Consulting. Mr. Kronfol serves on the boards of a number of private medical and technology companies. Mr. Kronfol received an A.B. in computer science from Princeton University and an M.B.A. from The Wharton School at the University of Pennsylvania.

We believe that Mr. Kronfol is qualified to serve on our board of directors due to his extensive experience as a private equity investor and as a director of companies in the medical device industry.

***Elizabeth H. Weatherman***. Ms. Weatherman has served on our board of directors since April 2013. Ms. Weatherman has been a Special Limited Partner of Warburg Pincus since January 2016. Ms. Weatherman previously was a Managing Director of Warburg Pincus and a member of the firm's Executive Management Group. Ms. Weatherman joined Warburg Pincus in 1988 and led the firm's Healthcare Group from 2008 to 2015. Ms. Weatherman serves on the board of directors of Wright Medical Group, N.V., and Vapotherm Inc., both publicly traded medical device companies. She serves on the Advisory Council of the Stanford Graduate School of Business, and on the board of trustees of Mount Holyoke College and Saint Ann's School in Brooklyn, NY. Ms. Weatherman received a B.A. from Mount Holyoke College and an M.B.A. from the Stanford Graduate School of Business.

We believe that Ms. Weatherman is qualified to serve on our board of directors due to her extensive experience as a private equity investor and a director of public companies in the medical device industry.

***Donald J. Zurbay***. Mr. Zurbay has served on our board of directors since March 2018. Mr. Zurbay has been Chief Financial Officer of Patterson Companies, Inc., a publicly traded global medical device company, since June 2018. From March 2004 to February 2017, Mr. Zurbay held various leadership positions at St. Jude Medical, Inc., where he most recently served as Vice President and Chief Financial Officer from August 2012 to January 2017. Mr. Zurbay previously worked at PricewaterhouseCoopers as an Assurance and Business Advisory Services Senior Manager. Prior to PricewaterhouseCoopers, he was a General Accounting Manager at The Valspar Corporation. Prior to The Valspar Corporation, Mr. Zurbay was an auditor at Deloitte & Touche. Mr. Zurbay is a member of the American Institute of Certified Accountants and the Minnesota Society of Certified Public Accountants. Mr. Zurbay received a B.S. in business with an emphasis in accounting from the University of Minnesota.

We believe that Mr. Zurbay is qualified to serve on our board of directors due to his current and prior experience at leading publicly traded healthcare companies, including as a Chief Financial Officer, and his financial experience and expertise.

## Executive Officers

Each of our executive officers serves at the discretion of our board of directors and holds office until his or her successor is duly elected and qualified or until his or her earlier resignation or removal. There are no family relationships among any of our directors or executive officers.

## Board of Directors

Our business is managed under the direction of our board of directors, which currently consists of eight directors. Our directors hold office until the earlier of their death, resignation, removal or disqualification, or until their successors have been elected and qualified. We do not have a chair of our board of directors. Our board of directors does not have a formal policy on whether the roles of chief executive officer and chair of our board of directors should be separate. Prior to the completion of this offering, the members of our board of directors were elected in compliance with the provisions of our amended and restated certificate of incorporation and a stockholders agreement among certain of our stockholders, and, under the terms of such stockholders agreement, the stockholders who are party to the stockholders agreement have agreed to vote their respective shares to elect: (1) one director who is our then-current Chief Executive Officer, currently Erica J. Rogers; (2) two directors designated by the holders of the Series A preferred stock, currently Tony M. Chou and Jack W. Lasersohn; (3) three directors designated by the holders of the Series B preferred stock, currently Amr Kronfol, Ruoxi Chen, and Donald Zurbay; and (4) two directors designated by the holders of the Series C preferred stock (one of whom shall be designated by Norwest subject to their ownership of at least 50% of the shares of Series C preferred stock purchased by them pursuant to the Series C Preferred Stock Purchase Agreement), currently Dr. Robert E. Mittendorff and Elizabeth H. Weatherman. Dr. Chou and Mr. Lasersohn were designated and appointed as directors by the Vertical Group; Messrs. Chen, Kronfol and Zurbay and Ms. Weatherman were appointed as directors by Warburg; and Dr. Mittendorff was appointed as a director by Norwest.

Upon completion of the offering, and for as long as Warburg and Vertical, respectively, own at least ten percent (10%) of our issued and outstanding common stock, we will nominate and use commercially reasonable efforts (including, without limitation, soliciting proxies for each designee of Warburg and Vertical to the same extent we do so for any of its other nominees to the board of directors) to have such number of individuals designated by each of Warburg and Vertical, respectively, elected to the board of directors so that the number of individuals designated by Warburg and Vertical, respectively, for election to the board of directors as compared to the size of the board of directors is proportionate to the number of shares of issued and outstanding common stock then owned by Warburg and Vertical, respectively, as compared to the number of shares of issued and outstanding common stock at such time; provided, however, that as long as each of Warburg and Vertical, respectively, own at least ten percent (10%) of the issued and outstanding common stock, each of Warburg and Vertical has the right to designate at least one (1) individual for election to our board of directors.

Upon the completion of this offering, our board of directors will be divided into three classes with staggered three-year terms. Our first annual meeting of stockholders will be in 2020. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election or until their earlier death, resignation or removal. Our directors will be divided among the three classes as follows:

- Class I directors will be Ms. Rogers and Messrs. Kronfol and Lasersohn, and their terms will expire at our annual meeting of stockholders to be held in 2020;
- Class II directors will be Dr. Mittendorff, Dr. Chou and Mr. Chen, and their terms will expire at our annual meeting of stockholders to be held in 2021; and
- Class III directors will be Mr. Zurbay and Ms. Weatherman, and their terms will expire at our annual meeting of stockholders to be held in 2022.

This classification of the board of directors, together with the ability of the stockholders to remove our directors only for cause and the inability of stockholders to call special meetings, may have the effect of delaying or preventing a change in control or management. See "Description of Capital Stock—Anti-Takeover Effects or Provisions of our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and Delaware Law" for a discussion of other anti-takeover provisions that will be included in our amended and restated certificate of incorporation that will become effective prior to the completion of this offering.

## Director Independence

Our common stock has been approved for quotation on The Nasdaq Stock Market. Under the rules of The Nasdaq Stock Market, independent directors must comprise a majority of a listed company's board of directors within a specified period of time after listing on The Nasdaq Stock Market. Under Nasdaq Listing Rule 5605(a)(2), a director will qualify as an "independent director" only if, in the opinion of the company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Our board of directors has reviewed the independence of each director and determined that Dr. Chou, Mr. Lasersohn, Dr. Mittendorff, Ms. Weatherman and Mr. Zurbay, representing five of our eight directors, are independent directors under the rules of The Nasdaq Stock Market. Our board of directors will review the independence of each director at least annually. During these reviews, the board of directors will consider transactions and relationships between each director, and his or her immediate family and affiliates, and our company and its management to determine whether any such transactions or relationships are inconsistent with a determination that the director is independent. This review will be based primarily on responses of the directors to questions in a directors' and officers' questionnaire regarding employment, business, familial, compensation and other relationships with our company including its management.

In addition, the rules of The Nasdaq Stock Market require that, subject to specified exceptions, each member of a listed company's audit, compensation, and nominating and governance committees be independent. In order to be considered independent for purposes of Rule 10A-3 under the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (i) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries; or (ii) be an affiliated person of the listed company or any of its subsidiaries. Members of the compensation committee must also satisfy additional independence requirements set forth in Nasdaq Listing Rule 5605(d)(2). In order to be considered independent for purposes of Nasdaq Listing Rule 5605 (d)(2), a member of a compensation committee of a listed company may not, other than in his or her capacity as a member of the compensation committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries. Additionally, the board of directors of the listed company must consider whether the compensation committee member is an affiliated person of the listed company or any of its subsidiaries and, if so, must determine whether such affiliation would impair the director's judgment as a member of the compensation committee.

We believe that a majority of our directors and the composition of our board of directors meets the requirements for independence under the current requirements of the SEC and The Nasdaq Stock Market. As required by The Nasdaq Stock Market, we anticipate that our independent directors will meet in regularly scheduled executive sessions at which only independent directors are present. We intend to comply with future governance requirements to the extent they become applicable to us.

## Corporate Governance

We believe that good corporate governance is important to ensure that, as a public company, we will be managed for the long-term benefit of our stockholders. In preparation for the offering being made by this prospectus, we and our board of directors have been reviewing the corporate governance policies and practices of other public companies, as well as those suggested by various authorities in corporate governance. We have also considered the provisions of the Sarbanes-Oxley Act and the rules of the SEC and The Nasdaq Stock Market.

Based on this review, our board of directors has taken steps to implement many of these provisions and rules. In particular, our board of directors has approved charters for the audit committee and compensation committee, as well as a code of business conduct and ethics applicable to all of our directors, officers and employees.

## Board Committees

Our board of directors has established a standing audit committee and a compensation committee. Our board of directors has assessed the independence of the members of each of these standing committees as defined under the rules of The Nasdaq Stock Market and, in the case of the audit committee, the independence requirements of Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or Exchange Act.

***Audit Committee***

Ms. Weatherman and Messrs. Chen and Zurbay serve on our audit committee. Mr. Zurbay serves as the chair of the audit committee. Our board of directors has determined that Ms. Weatherman and Mr. Zurbay meet the independence and experience requirements applicable to audit committee members under the rules of The Nasdaq Stock Market and the SEC and that Mr. Zurbay is an “audit committee financial expert” as defined under applicable rules of the SEC. Our board of directors has assessed whether all members of the audit committee meet the composition requirements of The Nasdaq Stock Market, including the requirements regarding financial literacy and financial sophistication. Our board of directors found that Ms. Weatherman and Messrs. Chen and Zurbay have met the financial literacy and financial sophistication requirements under SEC and The Nasdaq Stock Market rules. Mr. Chen is currently not considered to be an independent audit committee member within the meaning of applicable SEC and Nasdaq rules, but our board has determined to keep him on the audit committee based on his qualifications and experience. As a result, Mr. Chen does not fall under the safe harbor provision of Rule 10A-3 of the Exchange Act and is not considered independent under such rule. Until we locate a suitable replacement for Mr. Chen, we plan to rely on SEC and Nasdaq rules for phasing in new independent audit committee members. The audit committee’s primary responsibilities include:

- Appointing, approving the compensation of, and assessing the qualifications and independence of our independent registered public accounting firm, which currently is PricewaterhouseCoopers LLP;
- Reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- Preparing the audit committee report required by SEC rules to be included in our annual proxy statements;
- Monitoring our internal control over financial reporting, disclosure controls and procedures;
- Reviewing our risk management status;

- Establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- Meeting independently with our independent registered public accounting firm and management; and
- Monitoring compliance with the code of business conduct and ethics for financial management.

All audit and non-audit services must be approved in advance by the audit committee. Our board of directors has adopted a written charter for the audit committee, which will be available on our website upon the completion of this offering.

***Compensation Committee***

Dr. Mittendorff and Messrs. Chen and Lasersohn serve on our compensation committee. Mr. Lasersohn serves as the chair of the compensation committee. Dr. Mittendorff and Mr. Lasersohn meet the independence requirements of Nasdaq Rule 5605(d)(2). Mr. Chen is not currently considered to be independent and our board has determined to keep Mr. Chen on the compensation committee in reliance on Nasdaq Rule 5605(d)(2)(B). The compensation committee's responsibilities include:

- Annually reviewing and approving corporate goals and objectives relevant to compensation of our chief executive officer and our other executive officers;
- Annually reviewing and making recommendations to our board of directors with respect to the compensation of our chief executive officer and determining the compensation for our other executive officers;
- Reviewing and making recommendations to our board of directors with respect to director compensation; and
- Overseeing and administering our equity incentive plans.

Our chief executive officer and our vice president of human resources make compensation recommendations for our other executive officers and initially proposes the corporate and departmental performance objectives under our Executive Incentive Compensation Plan to the compensation committee. From time to time, our compensation committee may use outside compensation consultants to assist it in analyzing our compensation programs and in determining appropriate levels of compensation and benefits. For example, in the fourth quarter of 2018, we engaged Compensia, Inc., to advise us on compensation philosophy as we transition towards becoming a publicly-traded company, selection of a group of peer companies to use for compensation benchmarking purposes and cash and equity compensation levels for our directors, executives and other employees based on current market practices. Our board of directors has adopted a written charter for the compensation committee, which will be available on our website upon the completion of this offering.

***Nominating and Corporate Governance Matters***

Our board of directors does not currently have a nominating and corporate governance committee or other committee performing a similar function, nor do we have any formal written policies outlining the factors and process relating to the selection of nominees for consideration for membership on our board of directors by our directors or our stockholders. Our board of directors has adopted resolutions in accordance with the rules of The Nasdaq Stock Market authorizing a majority of our independent members to recommend qualified director nominees for consideration by the board of directors. Our board of directors believes that it is appropriate for us to not have a standing nominating and corporate governance committee because of a number of factors, including the number of independent members

who want to participate in consideration of candidates for membership on our board of directors and in matters that relate to the corporate governance of our company. Our board of directors consists of eight members, five of whom are independent. Our board of directors considered forming a nominating and corporate governance committee consisting of several of the independent members of our board of directors. Forming a committee consisting of less than all of the independent members was unattractive because it would have omitted the other independent members of our board of directors who wanted to participate in considering qualified candidates for board membership and to have input on corporate governance matters related to our company. Since our board of directors desired the participation in the nominations process of all of its independent directors, it therefore decided not to form a nominating and corporate governance committee and instead authorized a majority of the independent members of our board of directors to make and consider nominations for membership to our board of directors. The independent members of our board of directors do not have a nominating and corporate governance committee charter, but act pursuant to board of director resolutions as described above. Each of the members of our board of directors authorized to recommend director nominees is independent within the meaning of the current "independent director" standards established by The Nasdaq Stock Market rules. Our board of directors intends to review this matter periodically, and may in the future elect to designate a formal nominating and corporate governance committee.

## Code of Business Conduct and Ethics

Our board of directors has adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Following the completion of this offering, our code of business conduct and ethics will be available on our website at www.silkroadmed.com. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website to the extent required by the applicable rules and exchange requirements. The inclusion of our website address in this prospectus does not incorporate by reference into this prospectus the information on or accessible through our website.

## Limitation on Liability and Indemnification Matters

Our board of directors expects to adopt an amended and restated certificate of incorporation, which will become effective prior to the completion of this offering, contains provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by Delaware law. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- Any breach of the director's duty of loyalty to us or our stockholders;
- Any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- Unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- Any transaction from which the director derived an improper personal benefit.

Our board of directors has adopted an amended and restated certificate of incorporation and amended and restated bylaws, which will become effective prior to the completion of this offering, and it provides that we are required to indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. Our amended and restated bylaws also provides that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permits us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under Delaware law. We have entered, and expect to continue to enter, into agreements to indemnify our directors, executive officers and other employees as determined

by our board of directors. With specified exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and our stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damages.

## Compensation Committee Interlocks and Insider Participation

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or its compensation committee. None of the current members of the compensation committee of our board of directors has been one of our employees within the past five years.

## Director Compensation

Prior to the completion of this offering, except for Donald Zurbay, non-employee members of our board of directors did not receive any cash compensation for service on our board of directors or committees, including attending board and committee meetings. However, we did reimburse our non-employee directors for travel, lodging and other reasonable expenses incurred in attending board, committee and other company related meetings. In addition, from time to time we have granted stock options to some of our directors.

The following table sets forth a summary of the compensation received by our directors that are not also employees of our company during our fiscal year ended December 31, 2018:

| Name | Fees Earned or Paid in Cash ($) | Option Awards ($) [1] | Total ($) |
|---|---|---|---|
| Donald Zurbay | $ 46,667 | $ 301,573 | $ 348,240 |

(1) The amount reported represents the aggregate grant-date fair value of the stock options awarded, calculated in accordance with ASC Topic 718. Such grant-date fair value does not take into account any estimated forfeitures related to service-vesting conditions. The assumptions used in calculating the grant-date fair value of the options reported in this column are set forth in "Management's Discussion and Analysis of Financial Condition and Results of Operations-Critical Accounting Policies and Estimates-Common Stock Valuation and Stock-Based Compensation."

Directors who are also our employees receive no additional compensation for their service as directors. During 2018, Erica J. Rogers, who is one of our directors, was also an employee of our company. See "Executive Compensation—Summary Compensation Table" for additional information about the compensation for Ms. Rogers.

***Outside Director Compensation Policy***

After the completion of this offering, each non-employee director will be eligible to receive compensation for his or her service consisting of annual cash retainers and equity awards. Our board of directors will have the discretion to revise non-employee director compensation as it deems necessary or appropriate.

*Cash Compensation*. All non-employee directors will be entitled to receive the following cash compensation for their services following the completion of this offering:

- $40,000 per year for services as a board member;
- $46,000 per year additionally for service as chairman of the board of directors;
- $20,000 per year additionally for service as chairman of the audit committee;
- $8,000 per year additionally for service as an audit committee member;
- $15,000 per year additionally for service as chairman of the compensation committee; and
- $6,000 per year additionally for service as a compensation committee member.

Each annual cash retainer and additional annual fee will be paid quarterly in arrears on a prorated basis.

Each non-employee director may also elect to receive all or part of his or her cash retainer and additional fee payments in the form of stock options under our 2019 Equity Incentive Plan. Elections to convert cash retainer and additional fee payments into options with respect to services to be performed during the period commencing on the date of an annual meeting of our stockholders, or an Annual Meeting, and ending on the following year's Annual Meeting must generally be made on or prior to December 31st of the year prior to the year in which such annual period commences, or such earlier deadline as established by our board of directors or compensation committee (an "annual election"). Each individual who first becomes a non-employee director is permitted to elect to convert cash retainer and additional fee payments payable in the same calendar year through the date of the following year's Annual Meeting into options, provided that the election is made prior to the date the individual becomes a non-employee director (an "initial election"). In connection with this offering, each non-employee director may also elect to convert cash retainer and additional fee payments payable from June 1, 2019 through the date of the Annual Meeting in 2020 into options, provided that the election was made prior to April 3, 2019 (an "IPO election").

All options granted in lieu of cash retainer and additional fee payments will vest in quarterly installments that generally track when cash retainer or additional fee payments would have been paid, with the final vesting event occurring on the date of the next Annual Meeting following the date of grant. Options granted in connection with an annual election will generally be granted on the date of the next Annual Meeting following the calendar year in which the election is made. Options granted in connection with an initial election will generally be granted either on the fifth of the month following the month of the individual's election or appointment to our board of directors or on the date of the next Annual Meeting that occurs in the same calendar year as the individual's election or appointment to our board of directors. Options granted in connection with an IPO election will be granted on June 5, 2019.

*Equity Compensation*. Non-employee directors will be entitled to receive all types of awards (except incentive stock options) under the 2019 Equity Incentive Plan, or the 2019 Plan (or the applicable equity plan in place at the time of grant), including discretionary awards not covered under the outside director compensation policy. Following the completion of this offering, nondiscretionary, automatic grants of stock options will be made to our non-employee directors as follows:

- *Initial* Option Grant. Each person who first becomes a non-employee director after the completion of this offering will be granted an award of stock options with a value of $175,000 or an Initial Award.
- *Annual* Option Grant. Each non-employee director will be granted an award of stock options with a value of $100,000 on the date of each Annual Meeting, beginning with the 2020 Annual Meeting.

The "value" for the options described above means the grant date fair value calculated in accordance with the Black-Scholes option valuation methodology, or such other methodology our board of directors or compensation committee may determine. The term of each option described above will be ten years from the date of grant, subject to earlier termination as provided in the 2019 Plan. The exercise price per share of each option will equal 100% of the fair market value of one share of our common stock on the date of grant.

Subject to the applicable provisions of the 2019 Plan as further described under the section titled "Employee Benefit and Stock Plans," (i) each Initial Option Grant will be scheduled to vest as to one-third of the shares subject to such Initial Option Grant on each annual anniversary of the date the applicable non-employee's service as a non-employee director commenced, subject to the non-employee director continuing to provide services to the Company through the applicable vesting date, (ii) each Annual Option Grant will be scheduled to vest on the earlier of (a) the annual anniversary of the date of grant of such Annual Option Grant, or (b) the day immediately prior to the Annual Meeting next following the date the Annual Option is granted, provided that for either (a) or (b), the non-employee director has remained in continuous service with the Company through the applicable vesting date, and (iii) each Initial Option Grant and Annual Option Grant will fully vest if the company experiences a merger or change in control; provided that the non-employee director has remained in continuous service with the Company through such date. Additionally, pursuant to our outside director policy, in the event of a change of control, each outstanding and unvested equity award held by a non-employee director will accelerate and fully vest.

Pursuant to our outside director compensation policy, no non-employee director may be issued, in any fiscal year, cash compensation and equity awards with an aggregate value greater than $500,000, increased to $1,000,000 for the fiscal year an individual initially becomes a member of our board of directors. Any cash compensation paid or equity awards granted to an individual for his or her services as an employee, for his or her services as a consultant (other than as a non-employee director), will not count for purposes of this limitation.

# EXECUTIVE COMPENSATION

## Summary Compensation Table

This discussion contains forward looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt may differ materially from currently planned programs as summarized in this discussion. As an "emerging growth company" as defined in the JOBS Act, we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

The following table provides information regarding the total compensation for services rendered in all capacities that was earned by our principal executive officer and our two other most highly compensated executive officers who were serving as executive officers as of December 31, 2018. These individuals were our named executive officers for 2018.

| Name and Principal Position | Year | Salary ($) | Bonus ($)[1] | Stock Awards ($) | Option Awards ($)[2] | Non-Equity Incentive Plan Compensation ($)[3] | Non-Qualified Deferred Compensation Earnings ($) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|---|---|---|---|
| **Erica J. Rogers**<br>*President, Chief Executive Officer and Director* | 2018 | $ 390,000 | $ 234,000 | $ — | $ — | $ 234,000 | $ — | $ — | $ 624,000 |
| **Lucas W. Buchanan**<br>*Chief Financial Officer* | 2018 | 350,000 | 210,000 | — | — | 210,000 | — | — | 560,000 |
| **Andrew S. Davis**<br>*Executive Vice President, Global Sales and Marketing* | 2018 | 415,000 | 199,000 | — | 12,067 | 199,000 | — | — | 626,067 |

(1) Amounts reflect a year-end discretionary bonus paid on February 15, 2019.

(2) The amounts reported represent the aggregate grant-date fair value of the stock options awarded to the named executive officers in 2018, calculated in accordance with ASC Topic 718. Such grant-date fair value does not take into account any estimated forfeitures related to service-vesting conditions. The assumptions used in calculating the grant-date fair value of the options reported in this column are set forth in "Management's Discussion and Analysis of Financial Condition and Results of Operations-Critical Accounting Policies and Estimates-Common Stock Valuation and Stock-Based Compensation."

(3) Bonus amounts for 2018 for all named executive officers were paid on February 15, 2019, pursuant to our 2018 Bonus Plan, as described in the section below titled "Executive Compensation--Non-Equity Incentive Plan Compensation."

## Non-Equity Incentive Plan Compensation

We provide each of our named executive officers an opportunity to receive formula-based incentive payments. The payments are based on a target incentive amount for each named executive officer.

### *Non-Equity Incentive Payments for 2018*

For 2018, the target incentive amount and year-end payments for Erica J. Rogers, Lucas W. Buchanan and Andrew S. Davis under our 2018 Bonus Plan were as follows:

| Named Executive Officer | Target Award ($) | Actual Award Amount ($) |
|---|---|---|
| Erica J. Rogers | $ 117,000 | $ 234,000 |
| Lucas W. Buchanan | 105,000 | 210,000 |
| Andrew S. Davis | 145,250 | 199,000 |

The 2018 Bonus Plan provided for non-equity incentive compensation based upon our achievement of performance goals for 2018. The actual target incentive payments were weighted 100% toward achievement of Company goals which included achieving revenue targets, new account opening goals, threshold reorder rates, physician training goals, clinical outcome targets in ROADSTER 2, and product development goals.

## Pension Benefits and Nonqualified Deferred Compensation

We do not provide a pension plan for our employees, and none of our named executive officers participated in a nonqualified deferred compensation plan in 2018.

## Outstanding Equity Awards at 2018 Year-End

The following table sets forth information regarding outstanding stock options and stock awards held by our named executive officers as of December 31, 2018:

| | Option Awards | | | | | | Stock Awards | |
|---|---|---|---|---|---|---|---|---|
| Name | Grant Date[1] | Vesting Commencement Date[2] | Number of Securities Underlying Unexercised Options (#) Exercisable | Number of Securities Underlying Unexercised Options (#) Unexercisable | Option Exercise Price ($)[3] | Option Expiration Date | Number of Shares or Units of Stock That Vested (#) | Market Value of Shares or Units of Stock That Have Not Vested ($) |
| *Erica J. Rogers* | 12/14/2012 | 10/23/2012 | 121,597 | — | $ 1.38 | 12/14/2022 | — | — |
| | 12/14/2012 | 10/23/2012 | 82,512 | — | $ 1.38 | 12/14/2022 | — | — |
| | 12/24/2014 | 12/24/2014 | 61,728 | — | $ 1.46 | 12/24/2024 | — | — |
| | 12/3/2015 | 12/3/2015 | 107,467 | 35,822 | $ 1.60 | 12/13/2025 | — | — |
| | 8/4/2016 | 8/4/2016 | 151,234 | 108,024 | $ 1.60 | 8/4/2026 | — | — |
| | 11/30/2017 | 8/1/2017 | 24,691 | 49,382 | $ 6.11 | 11/30/2027 | — | — |
| | 11/30/2017 | 8/1/2017 | 122,222 | 244,444 | $ 12.15 | 11/30/2027 | — | — |
| | 11/30/2017 | 8/1/2017 | — | 22,222 | $ 12.15 | 11/30/2027 | — | — |
| *Lucas W. Buchanan* | 12/24/2014 | 12/24/2014 | 9,242 | — | $ 1.46 | 12/24/2024 | — | — |
| | 12/3/2015 | 12/3/2015 | 226,995 | — | $ 1.60 | 12/3/2025 | — | — |
| | 8/4/2016 | 8/4/2016 | 29,166 | 20,833 | $ 1.60 | 8/4/2026 | — | — |
| | 11/30/2017 | 8/1/2017 | 28,719 | 57,438 | $ 4.73 | 11/30/2027 | — | — |
| | 11/30/2017 | 8/1/2017 | 11,230 | 22,459 | $ 12.15 | 11/30/2027 | — | — |
| | 11/30/2017 | 8/1/2017 | — | 25,847 | $ 12.15 | 11/30/2027 | — | — |
| *Andrew S. Davis* | 6/23/2015 | 5/5/2015 | 124,425 | — | $ 1.46 | 6/23/2025 | — | — |
| | 12/3/2015 | 12/3/2015 | 34,335 | 11,445 | $ 1.60 | 12/3/2025 | — | — |
| | 11/30/2017 | 8/1/2017 | — | 36,111 | $ 4.73 | 11/30/2027 | — | — |
| | 11/30/2017 | 8/1/2017 | 28,104 | 56,172 | $ 4.73 | 11/30/2027 | — | — |
| | 9/13/2018 | 8/1/2018 | — | 2,962 | $ 6.11 | 9/13/2028 | — | — |

(1) Each of the outstanding equity awards was granted pursuant to our 2007 Stock Plan.

(2) Options generally vest over four years from the vesting commencement date in 48 equal monthly amounts, subject to continued service through each such vesting date, provided that the option grants to (x) Ms. Rogers on November 30, 2017 for 74,073 and 388,888 shares, respectively, (y) Mr. Buchanan on November 30, 2017, for 86,157 and 59,536 shares, respectively, and (z) Mr. Davis on November 30, 2017, for 120,387 shares will accelerate and fully vest if the applicable optionee experiences an involuntary termination under certain circumstances within the 12 month period following a change in control of the Company. The option grants to (i) Ms. Rogers on November 30, 2017, for 22,222 shares, (ii) Mr. Buchanan on November 30, 2017, for 25,847 shares and (iii) Mr. Davis on November 30, 2017, for 36,111 shares all vest upon the earlier of a change in control of the Company or the two year anniversary of the initial public offering of the Company's common stock, provided that each such option will accelerate and fully vest upon the involuntary termination of the applicable optionee under certain circumstances. The option grant to Mr. Buchanan on December 3, 2015 for 226,995 shares vested 85,123 shares on the vesting commencement date and the remaining shares vested over thirty months from the vesting commencement date in equal monthly amounts. The option grants to Mr. Davis on June 23, 2015 and September 13, 2018 for 138,893 shares and 2,962 shares, respectively, vest over four years from the vesting commencement date, with 25% vested on the one year anniversary of the vesting commencement date, and with the remaining amount vesting monthly over the subsequent 36 months in equal amounts.

(3) This column represents the fair market value of our common stock on the date of grant, as determined by our board of directors.

## Executive Officer Confirmatory Employment Letters

In March 2019, we entered into confirmatory employment letters with each of our named executive officers. Each letter has no specific term and provides for at-will employment. Each letter also provides that for our 2019 fiscal year, the applicable employee will have the opportunity to earn a target annual cash bonus based on achieving performance objectives established by our board of directors or compensation committee equal to a percentage of the employee's annual base salary, with such percentage being 60% for Ms. Rogers, 50% for Mr. Buchanan, and 50% for Mr. Davis, respectively. Each letter also provides for an annual base salary, with such salary being $430,000 for Ms. Rogers, $370,000 for Mr. Buchanan, and $435,000 for Mr. Davis.

## Executive Officer Change in Control and Severance Agreements

In March 2019, we entered into change of control and severance agreements with each of our named executive officers, which superseded all previous severance and change of control arrangements we had entered into with these employees. Each of these agreements has a term of three years. Under each of these agreements, if, within the period three months prior to and 12 months following a "change of control" (such period, the change in control period), we terminate the employment of the applicable employee without "cause" (excluding by reason of the employee's death or "disability,") or the employee resigns for "good reason" (as such terms are defined in the employee's change of control and severance agreement) and the employee executes a separation agreement and release of claims that becomes effective and irrevocable within 60 days following the employee's termination, the employee is entitled to receive (i) a lump sum severance payment, less applicable withholdings, equal to the payment of employee's base salary, as then in effect, of 18 months for Ms. Rogers, 12 months for Mr. Buchanan, and six months for Mr. Davis, respectively, plus, for Ms. Rogers and Mr. Davis, one additional month for each year the applicable employee has remained our employee through the termination date (with partial years of employment rounded up to a whole year), up to a limit of 24 months for Ms. Rogers and 12 months for Mr. Davis, respectively (such monthly period, the severance period) (ii) a lump sum payment, less applicable withholdings, equal to a percentage of the employee's annual target bonus for the year in which the termination occurs, with such percentage being 100% for Ms. Rogers and Mr. Buchanan and 50% for Mr. Davis, respectively, plus, for Ms. Rogers and Mr. Davis, 8.33% for each full year the applicable employee has remained our employee through the termination date (with partial years of employment rounded up to a whole year), up to a limit of 200% for Ms. Rogers and 100% for Mr. Davis, respectively, (iii) reimbursement of premiums to maintain group health insurance continuation benefits pursuant to "COBRA" for the employee and the employee's dependents through the applicable employee's severance period (with an additional limit of 18 months for Ms. Rogers), and (iv) accelerated vesting as to 100% of the employee's outstanding unvested equity awards.

In addition, under each of these agreements, if, outside of the change in control period, we terminate the employment of the applicable employee without cause (excluding by reason of the employee's death or disability), or the employee resigns for good reason, and the employee executes a separation agreement and release of claims that becomes effective and irrevocable within 60 days following the employee's termination, the employee is entitled to receive (i) a lump sum severance payment, less applicable withholdings, equal to the payment of, for Ms. Rogers and Mr. Buchanan, the employee's base salary, as then in effect, for 12 months for Ms. Rogers, nine months for Mr. Buchanan, respectively, and for Mr. Davis, six months of Mr. Davis' average total annualized cash compensation, as measured over the prior 12 month period preceding Mr. Davis' termination of employment, including salary, commissions and bonuses, and (ii) reimbursement of premiums to maintain group health insurance continuation benefits pursuant to "COBRA" for the employee and the employee's dependents for 12 months for Ms. Rogers, nine months for Mr. Buchanan, and six months for Mr. Davis, respectively.

Under each of these agreements, in the event any payment to the applicable employee pursuant to his or her change of control and severance agreement would be subject to the excise tax imposed by Section 4999 of the Internal Revenue Code, as amended, or the Code (as a result of a payment being

classified as a parachute payment under Section 280G of the Code), the employee will receive such payment as would entitle the employee to receive the greatest after-tax benefit, even if it means that we pay him or her a lower aggregate payment so as to minimize or eliminate the potential excise tax imposed by Section 4999 of the Code.

## Employee Benefit and Stock Plans

***2019 Equity Incentive Plan***

Our board of directors adopted, and our stockholders approved, our 2019 Equity Incentive Plan, or the 2019 Plan. Our 2019 Plan will become effective upon the completion of this offering. Our 2019 Plan permits the grant of incentive stock options, within the meaning of Section 422 of the Code, to our employees and any parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to our employees, directors and consultants and our parent and subsidiary corporations' employees and consultants.

*Authorized Shares*. A total of 2,317,000 shares of our common stock are reserved for issuance pursuant to the 2019 Plan. In addition, the shares reserved for issuance under our 2019 Plan will also include shares reserved but not issued under the 2007 Stock Plan, as amended, or the 2007 Plan, and shares subject to stock options or similar awards granted under the 2007 Plan that expire or terminate without having been exercised in full and shares issued pursuant to awards granted under the 2007 Plan that are forfeited to or repurchased by us (provided that the maximum number of shares that may be added to the 2019 Plan pursuant to this sentence is 4,170,676 shares). In addition, shares may become available under the 2019 Plan as described below.

The number of shares available for issuance under the 2019 Plan includes an annual increase on the first day of each fiscal year beginning in fiscal 2019, equal to the lesser of:

- 3,000,000 shares;
- 4% of the outstanding shares of common stock as of the last day of our immediately preceding fiscal year; or
- such other amount as our board of directors may determine.

If an award expires or becomes unexercisable without having been exercised in full, is surrendered pursuant to an exchange program, or, with respect to restricted stock, restricted stock units, performance units or performance shares, is forfeited or repurchased due to failure to vest, the unpurchased shares (or for awards other than stock options or stock appreciation rights, the forfeited or repurchased shares) will become available for future grant or sale under our 2019 Plan.

With respect to stock appreciation rights, the net shares issued will cease to be available under the 2019 Plan and all remaining shares will remain available for future grant or sale under the 2019 Plan. Shares used to pay the exercise price of an award or satisfy the tax withholding obligations related to an award will become available for future grant or sale under our 2019 Plan. To the extent an award is paid out in cash rather than shares, such cash payment will not result in reducing the number of shares available for issuance under our 2019 Plan.

*Plan Administration*. Our board of directors or one or more committees appointed by our board of directors will administer our 2019 Plan. In addition, if we determine it is desirable to qualify transactions under the 2019 Plan as exempt under Rule 16b-3 of the Exchange Act, or Rule 16b-3, such transactions will be structured to satisfy the requirements for exemption under Rule 16b-3. Subject to the provisions of our 2019 Plan, the administrator will have the power to administer our 2019 Plan and make all determinations deemed necessary or advisable for administering the 2019 Plan, such as the power to

determine the fair market value of our common stock, select the service providers to whom awards may be granted, determine the number of shares covered by each award, approve forms of award agreements for use under the 2019 Plan, determine the terms and conditions of awards (such as the exercise price, the times or times at which the awards may be exercised, any vesting acceleration or waiver or forfeiture restrictions, and any restriction or limitation regarding any award or the shares relating thereto), construe and interpret the terms of our 2019 Plan and awards granted under it, to prescribe, amend, and rescind rules relating to our 2019 Plan, including creating sub-plans, and to modify or amend each award, such as the discretionary authority to extent the post-termination exercisability period of awards (provided that no option or stock appreciation right will be extended past its original maximum term, and to allow a participant to defer the receipt of payment of cash or the delivery of shares that would otherwise be due to such participant under an award. The administrator also will have the authority to institute an exchange program by which (i) outstanding awards may be surrendered or cancelled in exchange for awards of the same type which may have a higher or lower exercise price and/or different terms, awards of a different type and/or cash, (ii) participants have the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator, or (iii) the exercise price of an outstanding award is increased or reduced. The administrator's decisions, interpretations, and other actions will be final and binding on all participants.

*Stock Options*. Stock options may be granted under our 2019 Plan. The exercise price of options granted under our 2019 Plan must at least be equal to the fair market value of our common stock on the date of grant. The term of an incentive stock option may not exceed 10 years, except that with respect to any participant who owns more than 10% of the voting power of all classes of our outstanding stock, the term must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. After the termination of service of an employee, director or consultant, he or she may exercise his or her option for the period of time stated in his or her option agreement. Generally, if termination is due to death or disability, the option will remain exercisable for 12 months. In all other cases, the option will generally remain exercisable for three months following the termination of service. However, in no event may an option be exercised later than the expiration of its term. Subject to the provisions of our 2019 Plan, the administrator determines the other terms of options.

*Stock Appreciation Rights*. Stock appreciation rights may be granted under our 2019 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. Stock appreciation rights may not have a term exceeding 10 years. After the termination of service of an employee, director or consultant, he or she may exercise his or her stock appreciation right for the period of time stated in his or her option agreement. However, in no event may a stock appreciation right be exercised later than the expiration of its term. Subject to the provisions of our 2019 Plan, the administrator determines the other terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination thereof, except that the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

*Restricted Stock*. Restricted stock may be granted under our 2019 Plan. Restricted stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted to any employee, director or consultant and, subject to the provisions of our 2019 Plan, will determine the terms and conditions of such awards. The administrator may impose whatever conditions for lapse of the restriction on the shares it determines to be appropriate (for example, the administrator may set restrictions based on the achievement of specific performance goals or continued service to us); provided, however, that the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Recipients of restricted stock awards generally will have voting and

dividend rights with respect to such shares upon grant without regard to the restriction, unless the administrator provides otherwise. Shares of restricted stock as to which the restrictions have not lapsed are subject to our right of repurchase or forfeiture.

*Restricted Stock Units.* Restricted stock units may be granted under our 2019 Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. Subject to the provisions of our 2019 Plan, the administrator will determine the terms and conditions of restricted stock units, including the vesting criteria (which may include accomplishing specified performance criteria or continued service to us) and the form and timing of payment. Notwithstanding the foregoing, the administrator, in its sole discretion, may accelerate the time at which any restricted stock units will vest.

*Performance Units and Performance Shares*. Performance units and performance shares may be granted under our 2019 Plan. Performance units and performance shares are awards that will result in a payment to a participant only if performance goals established by the administrator are achieved or the awards otherwise vest. The administrator will establish organizational or individual performance goals or other vesting criteria in its discretion, which, depending on the extent to which they are met, will determine the number and/or the value of performance units and performance shares to be paid out to participants. After the grant of a performance unit or performance share, the administrator, in its sole discretion, may reduce or waive any performance criteria or other vesting provisions for such performance units or performance shares.

Performance units shall have an initial dollar value established by the administrator prior to the grant date. Performance shares shall have an initial value equal to the fair market value of our common stock on the grant date. The administrator, in its sole discretion, may pay earned performance units or performance shares in the form of cash, in shares or in some combination

*Outside Directors*. Our 2019 Plan will provide that all outside (non-employee) directors will be eligible to receive all types of awards (except for incentive stock options) under our 2019 Plan. Prior to the completion of this offering, we intend to implement a formal policy pursuant to which our outside directors will be eligible to receive equity awards under our 2019 Plan. Our 2019 Plan includes a maximum annual limit of $500,000 of cash compensation and equity awards that may be paid, issued, or granted to an outside director in any fiscal year, increased to $1,000,000 for the fiscal year an individual initially becomes a member of our board of directors. For purposes of this limitation, the value of equity awards is based on the grant date fair value (determined in accordance with GAAP). Any cash compensation paid or equity awards granted to a person for his or her services as an employee, or for his or her services as a consultant (other than as an outside director), will not count for purposes of the limitation. The maximum limit does not reflect the intended size of any potential compensation or equity awards to our outside directors.

*Non-Transferability of Awards*. Unless the administrator provides otherwise, our 2019 Plan generally does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime. If the administrator makes an award transferable, such award will contain such additional terms and conditions as the administrator deems appropriate.

*Certain Adjustments*. In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under our 2019 Plan, the administrator will adjust the number and class of shares that may be delivered under our 2019 Plan and/or the number, class and price of shares covered by each outstanding award and the numerical share limits set forth in our 2019 Plan. In the event of our proposed liquidation or dissolution, the administrator will notify participants as soon as practicable and all awards will terminate immediately prior to the consummation of such proposed transaction.

*Merger or Change in Control*. Our 2019 Plan provides that in the event of a merger or change in control, as defined under our 2019 Plan, each outstanding award will be treated as the administrator determines, without a participant's consent. The administrator is not required to treat all awards, all awards held by a participant, or all awards of the same type, similarly.

In the event that a successor corporation or its parent or subsidiary does not assume or substitute an equivalent award for any outstanding award, then such award will fully vest, all restrictions on such award will lapse, all performance goals or other vesting criteria applicable to such award will be deemed achieved at 100% of target levels and such award will become fully exercisable, if applicable, for a specified period prior to the transaction, unless specifically provided for otherwise under the applicable award agreement or other written agreement with the participant. The award will then terminate upon the expiration of the specified period of time. If an option or stock appreciation right is not assumed or substituted, the administrator will notify the participant in writing or electronically that such option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion and the option or stock appreciation right will terminate upon the expiration of such period.

In addition, in the event of a change in control, each outside director's options and stock appreciation rights, if any, will vest fully and become immediately exercisable, all restrictions on his or her restricted stock and restricted stock units will lapse and all performance goals or other vesting requirements for his or her performance shares and units will be deemed achieved at 100% of target levels, and all other terms and conditions met.

*Forfeiture and Clawback.* All awards granted under our 2019 Plan will be subject to recoupment under any clawback policy that we are required to adopt under applicable law. In addition, the administrator will be able to provide in an award agreement that the recipient's rights, payments, and benefits with respect to such award will be subject to reduction, cancellation, forfeiture, or recoupment upon the occurrence of specified events. In the event of any accounting restatement, the recipient of an award will be required to repay a portion of the proceeds received in connection with the settlement of an award earned or accrued under certain circumstances.

*Amendment, Termination*. The administrator will have the authority to amend, suspend or terminate the 2019 Plan provided such action will not impair the existing rights of any participant. Our 2019 Plan will automatically terminate in 2029, unless we terminate it sooner.

***2019 Employee Stock Purchase Plan***

Our board of directors adopted, and our stockholders have approved, our 2019 Employee Stock Purchase Plan, or ESPP. Our ESPP became effective on April 2, 2019. We believe that allowing our employees to participate in our ESPP provides them with a further incentive towards ensuring our success and accomplishing our corporate goals.

The ESPP includes a component that is intended to qualify as an "employee stock purchase plan" under Section 423 of the Internal Revenue Code of 1986, as amended, or the 423 Component, and a component that does not comply with Section 423, or the Non-423 Component. For purposes of this disclosure, a reference to the "ESPP" will mean the 423 Component. Unless determined otherwise by the administrator, each of our future non-U.S. subsidiaries, if any, will participate in a separate offering under the Non-423 Component.

*Authorized shares*. A total of 434,000 shares of our common stock are available for sale. In addition, our ESPP provides for annual increases in the number of shares available for issuance under the ESPP on the first day of each fiscal year beginning in fiscal year 2019, equal to the lesser of:

- 1% of the outstanding shares of our common stock on the last day of the previous fiscal year;
- 1,200,000 shares; or
- such other amount as may be determined by our board of directors.

*Plan Administration*. Our board of directors, or a committee appointed by our board of directors will administer our ESPP, and have full but non-exclusive authority to interpret the terms of our ESPP and determine eligibility to participate, subject to the conditions of our ESPP, as described below. We expect our compensation committee to administer our ESPP. The administrator will have full and exclusive discretionary authority to construe, interpret, and apply the terms of the ESPP, to delegate ministerial duties to any of our employees, to designate separate offerings under the ESPP, to designate our subsidiaries and affiliates as participating in the ESPP, to determine eligibility, to adjudicate all disputed claims filed under the ESPP and to establish procedures that it deems necessary or advisable for the administration of the ESPP, such as adopting such procedures, sub-plans, and appendices to the enrollment agreement as are necessary or appropriate to permit participation in the ESPP by employees who are foreign nationals or employed outside the U.S. The administrator's findings, decisions, and determinations will be final and binding on all participants to the full extent permitted by law.

*Eligibility*. Generally, all of our employees will be eligible to participate if they are customarily employed by us, or any participating subsidiary, for at least 20 hours per week and more than five months in any calendar year. The administrator will have the discretion prior to an enrollment date for all options granted on such enrollment date in an offering, determine that an employee who (i) has not completed at least two years of service (or a lesser period of time determined by the administrator) since his or her last hire date, (ii) customarily works not more than 20 hours per week (or a lesser period of time determined by the administrator), (iii) customarily works not more than five months per calendar year (or a lesser period of time determined by the administrator), (iv) is a highly compensated employee within the meaning of Section 414(v) of the Code or is an officer or subject to disclosure requirements under Section 16(a) of the Exchange Act, is or is not eligible to participate in such offering period.

However, an employee may not be granted rights to purchase shares of our common stock under our ESPP if such employee:

- immediately after the grant would own capital stock possessing 5% or more of the total combined voting power or value of all classes of our capital stock; or
- hold rights to purchase shares of our common stock under all of our employee stock purchase plans that accrue at a rate that exceeds $25,000 worth of shares of our common stock for each calendar year.

*Offering Periods*. Our ESPP will include a component that allows us to make offerings intended to qualify under Section 423 of the Code and a component that allows us to make offerings not intended to qualify under Section 423 of the Code to designated companies, as described in our ESPP. Our ESPP will provide for six-month offering periods. The offering periods will be scheduled to start on the first trading day on or after May 20th and November 20th of each year, except for the first offering period, which will commence on the first trading day on or after completion of this offering and will end on the first trading day on or after November 20, 2019. Each offering period will consist of one 6-month purchase period, which will commence with one exercise date and end with the next exercise date.

*Contributions*. Our ESPP will permit participants to purchase shares of our common stock through payroll deductions of up to 10% of their eligible compensation. A participant will be able to purchase a maximum of 2,000 shares of our common stock during a purchase period.

*Exercise of Purchase Right*. Amounts deducted and accumulated by the participant will be used to purchase shares of our common stock at the end of each six-month purchase period. The purchase price of the shares will be 85% of the lower of the fair market value of our common stock on the first trading day of each offering period or on the exercise date. Participants will be able to end their participation at any time during an offering period and will be paid their accrued contributions that have not yet been used to purchase shares of our common stock. Participation will end automatically upon termination of employment with us.

*Non-Transferability*. A participant will not be able to transfer rights granted under our ESPP. If our compensation committee permits the transfer of rights, it may only be done by will, the laws of descent and distribution or as otherwise provided under our ESPP.

*Merger or Change in Control*. Our ESPP will provide that in the event of a merger or change in control, as defined under our ESPP, a successor corporation may assume or substitute each outstanding purchase right. If the successor corporation refuses to assume or substitute for the outstanding purchase right, the offering period then in progress will be shortened, and a new exercise date will be set that will be before the date of the proposed merger or change in control. The administrator will notify each participant that the exercise date has been changed and that the participant's option will be exercised automatically on the new exercise date unless prior to such date the participant has withdrawn from the offering period.

*Amendment; Termination*. The administrator will have the authority to amend, suspend or terminate our ESPP, except that, subject to certain exceptions described in our ESPP, no such action may adversely affect any outstanding rights to purchase shares of our common stock under our ESPP. Our ESPP automatically will terminate in fiscal year 2039 unless we terminate it sooner.

***2007 Stock Plan, as Amended***

Our board of directors adopted, and our stockholders approved, our 2007 Stock Plan, or the 2007 Plan, in March 2007. Our 2007 Plan was most recently amended in June 2018. Our 2007 Plan allows for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended, to our employees and our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options and shares of common stock to our employees, directors and consultants and our parent and subsidiary corporations' employees, directors and consultants.

*Authorized Shares*. Our 2007 Plan will be terminated in connection with this offering, and accordingly, no shares will be available for issuance under the 2007 Plan following the completion of this offering. Our 2007 Plan will continue to govern outstanding awards granted thereunder. As of December 31, 2018, options to purchase 4,362,935 shares of our common stock remained outstanding under our 2007 Plan. In the event that an outstanding option or other right for any reason expires or is canceled, the shares allocable to the unexercised portion of such option or other right shall be added to the number of shares then available for issuance under the 2019 Plan once adopted by our board of directors and our stockholders.

*Plan Administration*. Our board of directors or a committee of our board (the administrator) administers our 2007 Plan. Subject to the provisions of the 2007 Plan, the administrator has the full authority and discretion to take any actions it deems necessary or advisable for the administration of the 2007 Plan. All decisions, interpretations and other actions of the administrator are final and binding on all participants in the 2007 Plan.

*Options*. Stock options may be granted under our 2007 Plan. The exercise price per share of all options must equal at least 100% of the fair market value per share of our common stock on the date of grant, as determined by the administrator. The term of a stock option may not exceed 10 years. With respect to any participant who owns 10% of the voting power of all classes of our outstanding stock as of the grant date, the term of an incentive stock option granted to such participant must not exceed five years and the exercise price per share of such incentive stock option must equal at least 110% of the fair market value per share of our common stock on the date of grant, as determined by the administrator. The 2007 Plan administrator determines the terms and conditions of options.

After termination of an employee, director or consultant, he or she may exercise his or her option for the period of time as specified in the applicable option agreement. If termination is due to death or disability, the option generally will remain exercisable for at least six months. In all other cases, the option will generally remain exercisable for at least 30 days. However, an option generally may not be exercised later than the expiration of its term. Shares of Common Stock. Shares of our common stock may be granted under our 2007 Plan as a purchasable award. The administrator will determine the purchase price and the number of shares granted to the award recipient. Stock purchase rights generally must be exercised within 90 days of grant.

*Transferability of Awards*. Unless our administrator provides otherwise, our 2007 Plan generally does not allow for the transfer or assignment of options or stock purchase rights, except by will or by the laws of descent and distribution. Shares issued upon exercise of an option will be subject to such terms and conditions as the administrator may determine, including rights of first refusal and other transfer restrictions.

*Certain Adjustments*. In the event of a subdivision of our outstanding stock, a declaration of a dividend payable in shares, a combination or consolidation of our outstanding stock into a lesser number of shares, a reclassification, or any other increase or decrease in the number of issued shares of stock effected without receipt of consideration by us, the 2007 Plan will be appropriately adjusted by the administrator as to the class and maximum number of securities subject to the 2007 Plan and the class, number of securities and price per share of common stock subject to outstanding awards under the 2007 Plan, provided that our administrator will make any adjustments as may be required by Section 25102(o) of the California Corporations Code.

*Merger or Change in Control*. Our 2007 Plan provides that, in the event that we are a party to a merger or change in control, outstanding options and stock purchase rights may be assumed or substituted by the successor corporation or a parent or subsidiary thereof. In the event the successor corporation refuses to assume or substitute for the option or stock purchase right, then the vesting of such awards will be fully accelerated and the administrator will notify the holder in writing or electronically that such awards will be fully exercisable and vested for a period as determined by the administrator, and such awards will terminate upon expiration of such period.

*Amendment; Termination*. Our board of directors may amend, suspend or terminate our 2007 Plan at any time, provided that such action does not impair a participant's rights under outstanding awards without such participant's written consent. As noted above, upon completion of this offering, our 2007 Plan will be terminated and no further awards will be granted thereunder. All outstanding awards will continue to be governed by their existing terms.

***NeuroCo, Inc. 2015 Equity Incentive Plan***

In connection with our acquisition of NeuroCo, Inc. on December 17, 2018, our board of directors approved the assumption of the NeuroCo, Inc. 2015 Equity Incentive Plan, or the NeuroCo Plan.

*Authorized Shares*. The NeuroCo Plan was terminated on April 3, 2019, and, accordingly, no shares will be available for issuance under this plan. Our NeuroCo Plan will continue to govern outstanding

awards granted thereunder. As of December 31, 2018, options to purchase 1,442 shares of our common stock remained outstanding under the NeuroCo Plan.

*Plan Administration*. Our board of directors or a committee thereof appointed by our board of directors has the authority to administer the NeuroCo Plan. Subject to the provisions of the NeuroCo Plan, the administrator has the power to determine the terms of awards, including the recipients, the number of shares subject to each award, the exercise price, if any, the fair market value of a share of our common stock, the vesting schedule applicable to the awards, together with any vesting acceleration, and the terms of the award agreement for use under the NeuroCo Plan. The administrator also has the authority, subject to the terms of the NeuroCo Plan, to institute an exchange program under which (1) outstanding awards may be surrendered or cancelled in exchange for awards of the same type (which may have lower or higher exercise prices and different terms), awards of a different type and/or cash, (2) participants would have the opportunity to transfer any outstanding awards to a financial institution or other person or entity selected by the administrator and/or (3) the exercise price of an outstanding award is increased or reduced, to prescribe rules and regulations pertaining to the NeuroCo Plan, including establishing sub-plans for the purposes of satisfying applicable foreign laws, and to construe and interpret the NeuroCo Plan and awards granted thereunder.

*Stock Options*. Stock options may be granted under the NeuroCo Plan. The exercise price per share of all options must equal at least 100% of the fair market value per share of our common stock on the date of grant. The term of an option may not exceed 10 years. An incentive stock option held by an employee who owns more than 10% of the total combined voting power of all classes of our stock, or any parent or subsidiary corporations, may not have a term in excess of five years and must have an exercise price of at least 110% of the fair market value per share of our common stock on the date of grant. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares, promissory notes or certain other property or other consideration acceptable to the administrator. After the termination of service of an employee, director or consultant, the participant may exercise his or her option, to the extent vested as of such date of termination, within 30 days of termination or such longer period of time as stated in his or her option agreement. If termination is due to death or disability, the option will remain exercisable, to the extent vested as of such date of termination, for six months or such longer period of time as stated in his or her option agreement. However, in no event may an option be exercised later than the expiration of its term.

*Restricted Stock*. Restricted stock may be granted under the NeuroCo Plan. Restricted stock awards are grants of shares of our common stock that are subject to various restrictions, including restrictions on transferability and forfeiture provisions. Shares of restricted stock will vest, and the restrictions on such shares will lapse, in accordance with terms and conditions established by the administrator. Recipients of restricted stock awards will generally have rights equivalent to those of a stockholder with respect to such shares upon grant without regard to vesting.

*Restricted Stock Units*. Restricted stock units may be granted under the NeuroCo Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. The administrator determines the terms and conditions of restricted stock units including the vesting criteria, which may include accomplishing specified performance criteria or continued service to us, and the form and timing of payment. Notwithstanding the foregoing, the administrator, in its sole discretion may accelerate the time at which any restrictions will lapse or be removed.

*Stock Appreciation Rights*. Stock appreciation rights may be granted under the NeuroCo Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of shares of our common stock between the exercise date and the date of grant. Subject to the provisions of the NeuroCo Plan, the administrator determines the terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination thereof, except that the per share exercise price for the shares to be

issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

*Transferability of Awards*. Unless the administrator provides otherwise, the NeuroCo Plan generally does not allow for the transfer of awards other than by will or the laws of descent and distribution and only the recipient of an option may exercise such an award during his or her lifetime.

*Certain Adjustments*. In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under the NeuroCo Plan, the administrator will adjust the number and class of shares that may be delivered under the NeuroCo Plan and/or the number, class and price of shares covered by each outstanding award. In the event of our proposed liquidation or dissolution, the administrator will notify participants as soon as practicable, and all unexercised awards will terminate immediately prior to the consummation of such proposed transaction.

*Merger or Change in Control*. The NeuroCo Plan provides that in the event of a merger or change in control, as defined under the NeuroCo Plan, each outstanding award will be treated as the administrator determines, including, without limitation, that each award be assumed or substituted for an equivalent award. In the event that awards are not assumed or substituted for, then the administrator will notify holders that such awards will fully vest and such awards will become fully exercisable, if applicable, for a specified period prior to the transaction. The award will then terminate upon the expiration of the specified period of time for no consideration, unless otherwise determined by the administrator.

*Amendment, Termination*. Our board of directors may amend the NeuroCo Plan at any time, provided that such amendment does not impair the rights under outstanding awards without the award holder's written consent. As noted above, as of April 3, 2019, the NeuroCo Plan will be terminated and no further awards will be granted thereunder. All outstanding awards will continue to be governed by their existing terms.

***Executive Incentive Compensation Plan***

Our board of directors has adopted an Executive Incentive Compensation Plan, or the Bonus Plan, which will become effective upon the completion of this offering. The Bonus Plan will be administered by our compensation committee following the completion of this offering. The Bonus Plan allows our compensation committee to provide cash incentive awards to selected employees, including our named executive officers, based upon performance goals established by our compensation committee.

Under the Bonus Plan, our compensation committee determines the performance goals applicable to any award, which goals may include, without limitation: (i) attainment of research and development milestones, (ii) bookings, (iii) business divestitures and acquisitions, (iv) cash flow, (v) cash position, (vi) contract awards or backlog, (vii) customer renewals, (viii) customer retention rates from an acquired company, subsidiary, business unit or division, (ix) earnings (which may include earnings before interest and taxes, earnings before taxes, and net taxes), (x) earnings per share, (xi) expenses, (xii) gross margin, (xiii) growth in stockholder value relative to the moving average of the S&P 500 Index or another index, (xiv) internal rate of return, (xv) market share, (xvi) net income, (xvii) net profit, (xviii) net sales, (xix) new product development, (xx) new product invention or innovation, (xxi) number of customers, (xxii) operating cash flow, (xxiii) operating expenses, (xxiv) operating income, (xxv) operating margin, (xxvi) overhead or other expense reduction, (xxvii) product defect measures, (xxviii) product release timelines, (xxix) productivity, (xxx) profit, (xxxi) retained earnings, (xxxii) return on assets, (xxxiii) return on capital, (xxxiv) return on equity, (xxxv) return on investment, (xxxvi) return on sales, (xxxvii) revenue, (xxxviii) revenue growth, (xxxix) sales results, (xl) sales growth, (xli) stock price, (xlii) time to market, (xliii) total stockholder return, (xliv) working capital, a (xlv) individual objectives such as peer reviews or other subjective or objective criteria, (xlvi) clinical quality metrics, (xlvii) regulatory milestones related to the U.S. Food and Drug Administration, Centers for Medicare and Medicaid Services, or other government agencies, (xlviii) intellectual property milestones, (xlix) physician training, and (l) any other goals or metrics related to the

optimal management of a medical device company. Performance goals that include our financial results may be determined in accordance with GAAP or such financial results may consist of non-GAAP financial measures and any actual results may be adjusted by the compensation committee for one-time items or unbudgeted or unexpected items when performance goals that include our financial results may be determined in accordance with GAAP, or such financial results may consist of non-GAAP financial measures, and any actual results may be adjusted by the compensation committee for one-time items or unbudgeted or unexpected items when determining whether the performance goals have been met. The goals may be on the basis of any factors the compensation committee determines relevant, and may be adjusted on an individual, divisional, business unit or company-wide basis. The performance goals may differ from participant to participant and from award to award.

Our compensation committee may, in its sole discretion and at any time, increase, reduce or eliminate a participant's actual award, and/or increase, reduce or eliminate the amount allocated to the bonus pool for a particular performance period. The actual award may be below, at or above a participant's target award, in the compensation committee's discretion. Our compensation committee may determine the amount of any reduction on the basis of such factors as it deems relevant, and it is not required to establish any allocation or weighting with respect to the factors it considers.

Actual awards are paid in cash only after they are earned, which usually requires continued employment through the date a bonus is paid. Our compensation committee has the authority to amend, alter, suspend or terminate the Bonus Plan provided such action does not impair the existing rights of any participant with respect to any earned bonus.

***401(k) Plan***

We maintain a tax-qualified retirement plan that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis. We may make a discretionary matching contribution to the 401(k) plan, and may make a discretionary employer contribution to each eligible employee each year. To date, we have not made any matching or profits sharing contributions into the 401(k) plan. All participants' interests in their deferrals are 100% vested when contributed. Pre-tax contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. The 401(k) plan is intended to qualify under Sections 401(a) and 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the employees until distributed from the 401 (k) plan, and all contributions are deductible by us when made.

# CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS

Other than compensation arrangements, we describe below transactions and series of similar transactions, since January 1, 2016, to which we were a party or will be a party, in which:

- The amounts involved exceeded or will exceed $120,000; and
- Any of our directors, executive officers, or holders of more than 5% of our common stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Compensation arrangements for our directors and named executive officers are described elsewhere in this prospectus.

## Certain Transactions with Related Persons

During 2016, 2017 and 2018, the wife of Richard Ruedy, Executive Vice President of Clinical and Regulatory Affairs and Quality Assurance, was employed by the Company as Senior Director of Clinical and Regulatory Affairs. In 2016, Mr. Ruedy's wife earned total compensation of $190,000. In 2017, Mr. Ruedy's wife earned total compensation of $204,883. In 2018, Mr. Ruedy's wife earned total compensation and severance of $315,900. Total compensation includes salary and bonus. In 2019, Mr. Ruedy's wife transitioned to a regulatory consultant at a rate of $30,000 per month. She is expected to provide consulting services through March 31, 2019. The compensation of Mr. Ruedy's wife is consistent with that of other employees with equivalent qualifications and responsibilities and holding similar positions, and Mr. Ruedy recused himself from any decision regarding the hiring of, or compensation related to his wife.

## Series C Preferred Stock Financing

Between August 2014 and July 2017, we issued an aggregate 12,227,992 shares of our Series C preferred stock at a purchase price of $6.11 per share. The aggregate purchase price in the table below reflects the price paid for the Series C preferred stock only and not for the warrants. The shares of Series C preferred stock will convert into an aggregate of 12,227,992 shares of common stock upon the completion of this offering. The table below sets forth the number of shares of Series C preferred stock and the number of warrant shares issued in connection with our Series C preferred stock financing to our directors, executive officers and holders of more than 5% of our capital stock:

| Name | Number of Shares | Number of Warrant Shares | Aggregate Purchase Price |
|---|---|---|---|
| Entities affiliated with Warburg Pincus & Co.[1] | 5,904,180 | 2,214,626 | $36,027,324.24 |
| Entities affiliated with Janus[2] | 2,458,210 | - | 14,999,999.68 |
| Entities affiliated Norwest Venture Partners[3] | 2,458,210 | - | 14,999,999.68 |
| Entities affiliated with The Vertical Group, Inc.[4] | 656,015 | 246,067 | 4,003,022.74 |
| Elizabeth H. Weatherman | 163,880 | 40,970 | 999,995.76 |
| Erica J. Rogers [5] | 9,012 | 1,638 | 54,997.10 |
| Lucas W. Buchanan[6] | 18,843 | 4,915 | 114,993.32 |
| Andrew S. Davis | 12,290 | - | 74,998.10 |

(1) Affiliates of Warburg Pincus holding our securities, whose shares are aggregated for purposes of reporting the above share purchase information, are WP X Finance, L.P., which purchased 5,721,152 shares, and Warburg Pincus X Partners, L.P., which purchased 183,028 shares.

(2) Affiliates of Janus holding our securities, whose shares are aggregated for purposes of reporting the above share purchase information, are Buoybreeze + Co (a State Street Nominee), which purchased 1,610,446 shares, and Janus Capital Funds PLC on behalf of its Series Janus Global Life Sciences Fund, which purchased 847,764 shares.
(3) The affiliate of Norwest Venture Partners holding our securities is Norwest Venture Partners XIII, LP, which purchased 2,458,210 shares.
(4) Affiliates of the Vertical Group holding our securities, whose shares are aggregated for purposes of reporting the above share purchase information, are Vertical Fund I, L.P., which purchased 524,814 shares, and Vertical Fund II, L.P., which purchased 131,201 shares.
(5) Includes 9,012 shares held of record by The Surace/Rogers Family Trust, of which Erica J. Rogers, one of our executive officers, serves as trustee.
(6) Includes 10,651 shares held of record by the Buchanan Grandchildren's Irrevocable Trust, of which Mr. Buchanan, one of our executive officers, serves as trustee.

## Stockholders Agreement

In July 2017, in connection with the final closing of our Series C preferred stock financing, we entered into an amended and restated stockholders agreement with certain holders of our convertible preferred stock, including entities with which certain of our directors are affiliated.

## Registration Rights Agreement

In July 2017, in connection with the final closing of our Series C preferred stock financing, we entered into an amended and restated registration rights agreement with certain holders of our convertible preferred stock, including entities with which certain of our directors are affiliated. For a detailed description of registration rights under this agreement, see “Description of Capital Stock—Registration Rights.” Upon the completion of this offering, the information rights and right of first refusal under the stockholders agreement will terminate.

## Indemnification Agreements

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us to indemnify each director and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys’ fees, judgments, penalties, fines and settlement amounts incurred by the director or officer in any action or proceedings, including any action or proceeding by or in right of us, arising out of the person’s service as a director or officer. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

## NeuroCo Merger

We established a holding company, NeuroCo, Inc., to hold certain intellectual property and to undertake certain research and development activities. On December 17, 2018, we and NeuroCo entered into an Agreement and Plan of Merger pursuant to which we acquired all assets, including the assignment of all patents, and assumed all liabilities of NeuroCo. The merger closed on the same day and was consummated through a stock-for-stock transaction based on the relative values of our equity and NeuroCo’s equity. In consideration for 100% equity interest of NeuroCo, we issued 33,462 shares of our common stock, and a promissory note in the principal amount of approximately $1.6 million was settled and canceled. We assumed NeuroCo’s 2015 Equity Incentive Plan, or the NeuroCo Plan. As of the merger closing, the outstanding options to purchase common stock of NeuroCo under the NeuroCo Plan converted to options to purchase 1,442 shares of our common stock, and all outstanding warrants to purchase common stock of NeuroCo converted to warrants to purchase 7,527 shares of our common stock. As a result of the merger, NeuroCo merged into our company, with our company being the surviving corporation.

## Policies and Procedures for Related Party Transactions

Our board of directors has approved a policy, effective upon the completion of this offering, that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the prior consent of our audit committee. Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of any class of our common stock or any member of the immediate family of any of the foregoing persons in which the amount involved exceeds $120,000 and such person would have a direct or indirect interest must first be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our audit committee is to consider the material facts of the transaction, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction. We did not have a formal review and approval policy for related party transactions at the time of any of the transactions described above. However, all of the transactions described above were entered into after presentation, consideration and approval by our board of directors.

# PRINCIPAL AND SELLING STOCKHOLDERS

The following table provides information concerning beneficial ownership of our common stock as of December 31, 2018, assuming no exercise of the underwriters' option to purchase additional shares of our common stock from us, by:

- Each stockholder, or group of affiliated stockholders, that we know owns more than 5% of our outstanding common stock;
- Each of our named executive officers;
- Each of our directors; and
- All of our executive officers and directors as a group; and
- All selling stockholders

The percentage of shares beneficially owned is computed on the basis of 22,368,500 shares of our common stock outstanding as of December 31, 2018, which reflects the conversion of all of our outstanding shares of convertible preferred stock. Beneficial ownership is determined in accordance with the rules of the SEC, and generally includes voting power or investment power with respect to the securities held. We have deemed shares of our common stock subject to stock options that are currently exercisable or exercisable within 60 days of December 31, 2018, or issuable pursuant to the exercise of outstanding warrants to purchase shares of convertible preferred stock and common stock into shares of common stock to be outstanding and to be beneficially owned by the person holding the stock option or warrant for the purpose of computing the percentage ownership of that person. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Percentage ownership of our common stock after the offering assumes the sale of 6,000,000 shares by us in this offering. If the underwriters' option to purchase additional shares is exercised in full, entities affiliated with Warburg Pincus & Co. will offer 900,000 shares in this offering.

Except as indicated in the footnotes to this table, (i) the persons or entities named have sole voting and investment power with respect to all shares of our common stock shown as beneficially owned by them, and (ii) the address for each beneficial owner is c/o Silk Road Medical, Inc., 1213 Innsbruck Dr, Sunnyvale, CA 94089.

The selling stockholders have granted the underwriters an option exercisable for 30 days after the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of 900,000 shares from the selling stockholders at the public offering price less underwriting discounts and commissions.

| Name of Beneficial Owner | Shares Beneficially Owned Prior to the Offering | | Number of Shares Being Offered | Shares Beneficially Owned After the Offering (assuming no exercise of option) | | Shares Beneficially Owned After the Offering (assuming full exercise of option) | |
|---|---|---|---|---|---|---|---|
| | Number of Shares | Percentage | | Number of Shares | Percentage | Number of Shares | Percentage |
| **5% and Greater Stockholders:** | | | | | | | |
| Entities affiliated with Warburg Pincus & Co[1] | 13,776,199 | 56.0% | 900,000 | 13,776,199 | 45.0% | 12,876,199 | 42.1% |
| Entities affiliated with The Vertical Group, Inc.[2] | 4,279,690 | 18.9% | — | 4,279,690 | 15.0% | 4,279,690 | 15.0% |
| Entities affiliated with Norwest Venture Partners[3] | 2,461,974 | 11.0% | — | 2,461,974 | 8.7% | 2,461,974 | 8.7% |
| Entities affiliated with Janus[4] | 2,461,973 | 11.0% | — | 2,461,973 | 8.7% | 2,461,973 | 8.7% |
| **Named Executive Officers and Directors:** | | | | | | | |
| Erica J. Rogers[5] | 896,741 | 3.9% | — | 896,741 | 3.1% | 896,741 | 3.1% |
| Lucas W. Buchanan[7] | 406,270 | 1.8% | — | 406,270 | 1.4% | 406,270 | 1.4% |
| Andrew S. Davis[6] | 212,096 | * | — | 212,096 | * | 212,096 | * |
| Elizabeth H. Weatherman[8] | 270,996 | 1.2% | — | 270,996 | 1.0% | 270,996 | 1.0% |
| Tony M. Chou, M.D.[9] | 96,167 | * | — | 96,167 | * | 96,167 | * |
| Ruoxi Chen | — | * | — | — | * | — | * |
| Jack W. Lasersohn | — | * | — | — | * | — | * |
| Robert E. Mittendorff | — | * | — | — | * | — | * |
| Amr Kronfol | — | * | — | — | * | — | * |
| Donald J. Zurbay | — | * | — | — | * | — | * |
| All executive officers and directors as a group (10 persons)[10] | 1,882,270 | 7.9% | — | 1,882,270 | 6.3% | 1,882,270 | 6.3% |

* Represents ownership of less than 1%.

(1) Consists of (i) 358,405 shares of common stock and 68,652 common stock purchase warrants beneficially owned by Warburg Pincus X Partners, L.P. ("WPXP"), and (ii) 11,203,168 shares of common stock and 2,145,974 common stock purchase warrants beneficially owned by WP X Finance, L.P. ("WP X Finance"). WPX GP, L.P., a Delaware limited partnership ("WPX GP"), is the managing general partner of WP X Finance. Warburg Pincus Private Equity X, L.P., a Delaware limited partnership ("WP X"), is the general partner of WPX GP. Warburg Pincus X, L.P., a Delaware limited partnership ("WPX LP"), is the general partner of WPX and WPXP. Warburg Pincus X GP L.P., a Delaware limited partnership ("WP X GP LP"), is the general partner of WPX LP. WPP GP LLC, a Delaware limited liability company ("WPP GP"), is the general partner of WP X GP LP. Warburg Pincus Partners, L.P., a Delaware limited partnership ("WP Partners"), is the managing member of WPP GP. Warburg Pincus Partners GP LLC, a Delaware limited liability company ("WP Partners GP"), is the general partner of WP Partners. Warburg Pincus & Co., a New York general partnership ("WP"), is the managing member of WP Partners GP. Charles R. Kaye and Joseph P. Landy, are each Managing General Partners of WP and may each be deemed to control the Warburg Pincus entities. Messrs. Kaye and Landy disclaim beneficial ownership of all shares held by the Warburg Pincus entities. The business address for each of these entities and individuals is c/o Warburg Pincus & Co., 450 Lexington Avenue, New York, New York 10017.
Ruoxi Chen, a Principal at Warburg Pincus & Co., and Amr Kronfol, a Managing Director at Warburg Pincus & Co., are members of our board of directors, and both have no voting or dispositive power with respect to any of the above referenced shares and each disclaims beneficial ownership of such shares except to the extent of his or her respective pecuniary interest therein. All indirect holders of the above referenced shares disclaim beneficial ownership of all applicable shares except to the extent of their pecuniary interest therein.

(2) Consists of (i) 3,222,598 shares of common stock and 196,855 common stock purchase warrants beneficially owned by Vertical Fund I, L.P. ("Vertical I"), (ii) 810,284 shares of common stock and 49,212 common stock purchase warrants beneficially owned by Vertical Fund II, L.P. ("Vertical II"), and (iii) 741 shares of common stock beneficially owned by the Vertical Group, Inc. The Vertical Group, L.P., a Delaware limited partnership, is the sole general partner of each of VFI and VFII, and The Vertical Group GP, LLC, a Delaware limited liability company, controls The Vertical Group, L.P. The sole members and managers of The Vertical Group GP, LLC are Messrs. Tony M. Chou, Richard B. Emmitt, Jack W. Lasersohn and John E. Runnells, and these four individuals share voting and investment power over securities held by The Vertical Group, Inc., VFI and VFII. Mr. Lasersohn disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein. The address of The Vertical Group, L.P., The Vertical Group GP, LLC, VFI and VFII. is 106 Allen Road, Suite 207, Basking Ridge, NJ 07920.

(3) Consists of 2,461,974 shares of common stock beneficially owned by Norwest Venture Partners XIII, LP ("NVP XIII"). Genesis VC Partners XIII, LLC is the general partner of NVP XIII and may be deemed to have sole voting and dispositive power over the shares held by NVP XIII. NVP Associates, LLC, the managing member of Genesis VC Partners XIII, LLC and each of Promod Haque, Jeffrey Crowe and Jon Kossow, as Co-Chief Executive Officers of NVP Associates, LLC and members of the general partner, may be deemed to share voting and dispositive power over the shares held by NVP XIII. Such persons and entities disclaim beneficial ownership of the shares held by NVP XIII, except to the extent of any proportionate pecuniary interest therein. The address for these entities is 525 University Avenue, #800, Palo Alto, CA 94301.

Dr. Robert E. Mittendorff is a Partner at Norwest Venture Partners and is a member of our board of directors, and has no voting or dispositive power with respect to any of the above referenced shares and disclaims beneficial ownership of such shares except to the

extent of his respective pecuniary interest therein. All indirect holders of the above referenced shares disclaim beneficial ownership of all applicable shares except to the extent of their pecuniary interest therein.

(4) Consists of (i) 847,764 shares of common stock and 1,298 common stock purchase warrants owned by Janus Capital Funds PLC on behalf of its Series Janus Global Life Sciences Fund (“JCF”), and (ii) 1,610,446 shares of common stock and 2,465 common stock purchase warrants beneficially owned by Janus Henderson Global Life Sciences Fund (“Janus Global Life”) in the name of Buoybreeze + Co (a State Street Nominee). The shares owned by JCF, Janus Global Life and Buoybreeze (collectively, the "Funds") may be deemed to be beneficially owned by Janus Capital Management LLC (“Janus”), an investment advisor registered under the Investment Advisers Act of 1940, who acts as investment adviser for the Funds set forth above and has the ability to make decisions with respect to the voting and disposition of the shares subject to the oversight of the board of trustees (or similar entity) of each Fund. Under the terms of its management contract with each Fund, Janus has overall responsibility for directing the investments of the Fund in accordance with the Fund’s investment objective, policies and limitation. Each Fund has one or more portfolio managers appointed by and serving at the pleasure of Janus who makes decisions with respect to the disposition of the Shares. Similarly, State Street Bank is the custodian of Buoybreeze appointed by and serving at the pleasure of Janus. The address for Janus is 151 Detroit Street, 4th Floor, Denver, CO 80206.

(5) Consists of (i) 96,296 shares of common stock held directly by Ms. Rogers, (ii) 82,706 shares of common stock and 1,638 common stock purchase warrants held by Kevin J. Surace and Erica J. Rogers, as Trustees of The Surace/Rogers Family Trust, and (iii) 716,101 shares of common stock issuable pursuant to options held directly by Ms. Rogers exercisable within 60 days of December 31, 2018.

(6) Consists of (i) 12,290 shares of common stock held directly by Mr. Davis, and (ii) 199,806 shares of common stock issuable pursuant to options held directly by Mr. Davis exercisable within 60 days of December 31, 2018.

(7) Consists of (i) 75,380 shares of common stock and 2,048 common stock purchase warrants held directly by Mr. Buchanan, (ii) 10,651 shares of common stock and 2,867 common stock purchase warrants held by the Buchanan Grandchildren's Irrevocable Trust, and (iii) 315,324 shares of common stock issuable pursuant to options held directly by Mr. Buchanan exercisable within 60 days of December 31, 2018.

(8) Consists of (i) 163,880 shares of common stock and 40,970 common stock purchase warrants held directly by Ms. Weatherman, and (ii) 66,146 shares of common stock issuable pursuant to options held directly by Ms. Weatherman exercisable within 60 days of December 31, 2018.

(9) Consists of (i) 24,316 shares of common stock held directly by Dr. Chou, and (ii) 71,851 shares of common stock issuable pursuant to options held directly by Dr. Chou exercisable within 60 days of December 31, 2018.

(10) Consists of (i) 513,042 shares of common stock and common stock purchase warrants held by our current directors and officers and entities affiliated with certain of our current directors and officers, and (ii) 1,369,228 shares of common stock issuable pursuant to stock options held by such directors and officers and exercisable within 60 days of December 31, 2018.

# DESCRIPTION OF CAPITAL STOCK

The following summary describes our capital stock and the material provisions of our amended and restated certificate of incorporation and our amended and restated bylaws, which will become effective prior to the completion of this offering, the amended and restated investors rights agreement to which we and certain of our stockholders are parties, and of the Delaware General Corporation Law. This summary does not purport to be complete and is qualified in its entirety by the provisions of our amended and restated certificate of incorporation, amended and restated bylaws and amended and restated investors rights agreement, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part.

## General

Prior to the completion of this offering, we will file our amended and restated certificate of incorporation that authorizes 100 million shares of common stock, $0.001 par value per share, and 5 million shares of preferred stock, $0.001 par value per share. As of December 31, 2018, there were outstanding:

- 1,135,310 shares of our common stock held by approximately 67 stockholders of record;
- 21,233,190 shares of our common stock issuable upon conversion of outstanding shares of convertible preferred stock held by approximately 23 stockholders of record;
- 2,672,502 shares of our common stock issuable upon exercise of outstanding warrants to purchase convertible preferred stock;
- 7,527 shares of our common stock issuable upon exercise of outstanding warrants to purchase common stock; and
- 4,364,377 shares of our common stock issuable upon exercise of outstanding stock options.

Assuming the conversion of all of our outstanding shares of convertible preferred stock and the automatic net exercise of outstanding warrants to purchase shares of convertible preferred stock and common stock, as of December 31, 2018, in each case into common stock upon completion of this offering, at the initial public offering price of $20.00 per share, there were 24,228,959 shares of our common stock outstanding, held by approximately 79 stockholders of record and no shares of our convertible preferred stock outstanding. Upon the completion of this offering we expect to have 30,228,959 shares of common stock outstanding and no shares of preferred stock outstanding.

## Common Stock

### *Voting Rights*

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors.

### *Dividends*

Subject to preferences that may be applicable to any then outstanding convertible preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds. We do not have any plans to pay dividends to our stockholders.

***Liquidation***

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of convertible preferred stock.

***Rights and Preferences***

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our convertible preferred stock that we may designate in the future.

***Fully Paid and Nonassessable***

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

## Preferred Stock

Immediately prior to the completion of this offering, all outstanding shares of our convertible preferred stock will be converted into shares of our common stock. Upon the completion of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 5 million shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, rights and terms of redemption, liquidation preferences, sinking fund provisions and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. Immediately after completion of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

## Warrants

The following table sets forth information about outstanding warrants to purchase shares of our stock as of December 31, 2018. Immediately prior to the completion of this offering the warrants to purchase shares of our Series C preferred stock and common stock will be automatically net exercised for shares of our common stock, based on their conversion ratio, if not earlier exercised.

The warrants to purchase shares of our Series C preferred stock will expire upon the earlier of the expiration date set forth in each warrant, which are various dates between August 2022 and April 2024, our acquisition, a sale of all or substantially all our assets, or an initial public offering. We expect these warrants to be automatically net exercised in connection with this offering.

The warrants to purchase shares of our common stock will expire upon the earlier of the expiration date set forth in each warrant, which is November 2024, our acquisition, a sale of all or substantially all our assets, or an initial public offering. We expect these warrants to be automatically net exercised in connection with this offering.

| Class of Stock Underlying Warrants | Number of Shares of Stock Exercisable Prior to this Offering | Number of Shares of Common Stock Underlying Warrants on an As-Converted Basis | Exercise Price Per Share Prior to this Offering | Exercise Price Per Share on an As-Converted Basis |
|---|---|---|---|---|
| Series C convertible preferred stock, par value $0.001 | 2,672,502 | 2,672,502 | $ 6.11 | $ 6.11 |
| Common stock, par value $0.001 | 7,527 | 7,527 | $ 8.27 | $ 8.27 |
| Total | 2,680,029 | 2,680,029 | | |

## Registration Rights

After the completion of this offering, the holders of an aggregate of 22,800,622 shares of our common stock as of December 31, 2018 (including shares issuable upon the conversion of our outstanding convertible preferred stock immediately prior to the completion of this offering), will be entitled to certain rights with respect to the registration of such shares under the Securities Act. Beginning 180 days after the completion of this offering, the holders of at least a majority of these securities have the right to require us, on not more than two occasions, to file a registration statement on Form S-1 under the Securities Act in order to register the resale of their shares of common stock. We may, in certain circumstances, defer such registrations and the underwriters have the right, subject to certain marketing and other limitations, to limit the number of shares included in any underwritten offering. Further, the holders of these securities may require us to register the resale of all or a portion of their shares on a registration statement on Form S-3, subject to certain conditions and limitations.

In addition, the holders of these securities have certain “piggyback” registration rights. If we propose to register any of our equity securities under the Securities Act other than pursuant to the registration rights noted above or specified excluded registrations, holders may require us to include all or a portion of their registrable securities in the registration and in any related underwriting, subject to certain limitations. In an underwritten offering, the underwriters have the right, subject to specified conditions, to limit the number of registrable securities such holders may include. Additionally, piggyback registrations are subject to delay or termination of the registration under certain circumstances. The underwriters named in this prospectus have notified us that no holders of registration rights will be permitted to include any of their shares in this offering.

## Anti-Takeover Effects or Provisions of our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and Delaware Law

Some provisions of Delaware law and our amended and restated certificate of incorporation and our amended and restated bylaws that will be in effect prior to the completion of this offering contain provisions that could make the following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stock holders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the market price for our shares.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of a non-friendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

***Delaware Anti-Takeover Statute***

We are subject to Section 203 of the General Corporation Law of the State of Delaware, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- Before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested holder;
- Upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- On or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- Any merger or consolidation involving the corporation and the interested stockholder;
- Any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- Subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- Any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- The receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation or any entity or person affiliated with or controlling or controlled by such entity or person.

***Undesignated Preferred Stock***

The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any

attempt to acquire us. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

***Special Stockholder Meetings***

Our amended and restated bylaws provides that a special meeting of stockholders may be called only by our board of directors, the chairperson of our board of directors, or our Chief Executive Officer or President. This provision might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.

***Requirements for Advance Notification of Stockholder Nominations and Proposals***

Our amended and restated bylaws establishes advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors. Our amended and restated bylaws also specifies certain requirements regarding the form and content of a stockholder's notice.

*Advance Notice of Stockholder Business*

If a stockholder is submitting a stockholder proposal related to the business of the company, such stockholder must: (i) be a stockholder of record at the time notice is given, (ii) submit the notice in a timely manner, and (iii) such business must be of a proper matter for stockholder action in accordance with our bylaws and applicable law. To be in proper written form, a stockholder's notice related to the business of the company must contain the following items: (i) a brief description of the business intended to be brought before the annual meeting, the text of the proposed business (including the text of any resolutions proposed for consideration) and the reasons for conducting such business at the annual meeting, (ii) the name and address of the stockholder proposing such business, (iii) the class and number of shares that are held of record or are beneficially held by the stockholder, (iv) whether and the extent to which any hedging activities have been entered into by or on behalf of such stockholder with respect to our securities, (v) any material interest of the stockholder in such business, (vi) a statement whether such stockholder will deliver a proxy statement or form of proxy to holders required under applicable law to carry the proposal.

*Advance Notice of Director Nominations*

If a stockholder is submitting a nomination in connection with an annual meeting, such stockholder must: (i) be a stockholder of record at the time notice if given, and (ii) submit the notice in a timely manner. To be in proper written form, a stockholder's notice related to director nominations must contain the following items with respect to each nominee: (i) the name, age, business address and residence address of the nominee, (ii) the principal occupation or employment of the nominee, (iii) the class and number of shares of the company that are held of record or are beneficially owned by the nominee and any derivative positions held or beneficially held by the nominee, (iv) whether and the extent to which any hedging activities have been entered into by or on behalf of the nominee with respect to our securities, (v) a description of all arrangements or understandings between or among the stockholder, any nominee or any other person or persons pursuant to which the nominations are to be made by the stockholder and (vi) a written statement executed by the nominee acknowledging and representing that the nominee intends to serve a full term on our board of directors if elected. With respect to the stockholder, the notice must contain the following items: (i) the name and address of the stockholder proposing such business, (ii) the class and number of shares that are held of record or are beneficially held by the stockholder, (iiii) whether and the extent to which any hedging activities have been entered into by or on behalf of such stockholder with respect to our securities, (iv) any material interest of the stockholder in such business,

and (v) a statement whether such stockholder will deliver a proxy statement or form of proxy reasonably believed by such stockholder to be necessary to elect such nominee.

***Elimination of Stockholder Action by Written Consent***

Our amended and restated certificate of incorporation and our amended and restated bylaws eliminates the right of stockholders to act by written consent without a meeting. As a result, a holder controlling a majority of our capital stock would not be able to amend our amended and restated bylaws or remove directors without holding a meeting of our stockholders called in accordance with our amended and restated bylaws.

***Classified Board; Election and Removal of Directors***

Our amended and restated certificate of incorporation and amended and restated bylaws authorizes only our board of directors to fill vacant directorships, including newly created seats. In addition, the number of directors constituting our board of directors are permitted to be set only by a resolution adopted by our board of directors. These provisions prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management.

Upon the completion of this offering, our board of directors will be divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders, with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors up for election. In addition, our amended and restated certificate of incorporation provides that directors may only be removed for cause. For more information on the classified board, see “Management—Board of Directors.” This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

***Exclusive Forum***

Our amended and restated certificate of incorporation and bylaws will provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum, to the fullest extent permitted by law, for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against the company or any director or officer of the company arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or bylaws, or (4) any other action asserting a claim that is governed by the internal affairs doctrine shall be the Court of Chancery of the State of Delaware or federal court located within the State of Delaware if the Court of Chancery does not have jurisdiction, in all cases subject to the court’s having jurisdiction over indispensable parties named as defendants. A complaint asserting a cause of action under the Securities Act may be brought in state or federal court. With respect to the Securities Exchange Act of 1934, or Exchange Act, only claims brought derivatively under the Exchange Act would be subject to the forum selection clause described above. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation and bylaws has been challenged in legal proceedings, and it is possible that, in connection with any action, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation and bylaws to be inapplicable or unenforceable in such action. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits

against us or our directors and officers. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

***Amendment of Charter Provisions***

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least 66 2/3% of the voting power of our then outstanding voting stock.

The provisions of the Delaware General Corporation Law, our amended and restated certificate of incorporation and our amended and restated bylaws may have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

***Limitations on Liability and Indemnification Matters***

For a discussion of liability and indemnification, see “Management-Limitation on Liability and Indemnification Matters.”

***Exchange Listing***

Our common stock has been approved for quotation on The Nasdaq Global Market under the symbol “SILK.”

***Transfer Agent***

The transfer agent for our common stock will be American Stock Transfer & Trust Company, LLC. The transfer agent’s address is 6201 15th Avenue, Brooklyn, NY 11219. Our shares of common stock will be issued in uncertificated form only, subject to limited exceptions.

# SHARES ELIGIBLE FOR FUTURE SALE

Prior to the completion of this offering, there has been no public market for our common stock, and we cannot predict the effect, if any, that market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock prevailing from time to time. Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after the completion of this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Upon the completion of this offering, based on the number of shares of our capital stock outstanding as of December 31, 2018, we will have a total of 30,228,959 shares of our common stock outstanding, assuming the conversion of all of our outstanding shares of convertible preferred stock and the automatic net exercise of outstanding warrants to purchase shares of convertible preferred stock and common stock as of December 31, 2018, in each case into common stock upon completion of this offering, at the initial public offering price of $20.00 per share. Of these outstanding shares, all the shares of common stock sold in this offering, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable, unless purchased by our affiliates.

The remaining outstanding shares of our common stock will be deemed "restricted securities" as defined in Rule 144. Restricted securities may be sold in the public market only if they are registered or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, which rules are summarized below. In addition, holders of all or substantially all of our equity securities have entered into or will enter into lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions, not to sell any of our stock for at least 180 days following the date of this prospectus, as described below. As a result of these agreements, based on the number of shares of our capital stock outstanding as of December 31, 2018, subject to the provisions of Rule 144 or Rule 701, these restricted securities will be available for sale in the public market as follows:

- beginning on the date of this prospectus, all shares of common stock sold in this offering will be immediately available for sale in the public market; and
- beginning 181 days after the date of this prospectus, 24,228,959 additional shares of common stock will become eligible for sale in the public market, of which 22,723,499 shares will be held by affiliates and will be subject to the volume and other restrictions of Rule 144, as described below.

## Lock-Up Agreements

Our executive officers, directors and substantially all of our stockholders, including the selling stockholders, have entered into lock-up agreements with the underwriters of this offering under which they have agreed that, subject to certain exceptions, without the prior written consent of J.P. Morgan Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated, they will not dispose of or hedge any shares or any securities convertible into or exchangeable for shares of common stock for a period of 180 days from the date of this prospectus. See the section titled "Underwriting" for additional information.

J.P. Morgan Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated, may, in their discretion, release any of the securities subject to these lock-up agreements at any time without notice. Following the expiration of the lock-up period, and assuming that the representatives of the underwriters do not release any parties from these agreements, all of the shares of our common stock that are restricted securities or are held by our affiliates as of the date of this prospectus will be eligible for sale in the public market subject to the limitations of Rule 144 under the Securities Act.

## Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to the public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell those shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then that person would be entitled to sell those shares without complying with any of the requirements of Rule 144.

In general, under Rule 144, as currently in effect, and upon expiration of the lock-up agreements described above, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell within any three-month period, a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 302,289 shares immediately after this offering, assuming no exercise by the underwriters' option to purchase additional shares; or
- the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to that sale;

provided, in each case, that we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

## Rule 701

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares pursuant to Rule 701.

## Registration Rights

Pursuant to a registration rights agreement, the holders of an aggregate of 22,800,622 shares of our common stock as of December 31, 2018 (including shares issuable upon the conversion of our outstanding convertible preferred stock immediately prior to the completion of this offering), or their transferees, will be entitled to certain rights with respect to the registration of the offer and sale of those shares under the Securities Act. See "Description of Capital Stock—Registration Rights" for a description of these registration rights. If the offer and sale of these shares is registered, the shares will be freely tradable without restriction under the Securities Act, and a large number of shares may be sold into the public market.

## Stock and Option Plans

Following the completion of this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register shares of our common stock issued or reserved for issuance under our

2007 Stock Plan, 2019 Equity Incentive Plan and 2019 Employee Stock Purchase Plan, or the Plans. The registration statement on Form S-8 will become effective immediately upon filing, and shares covered by such registration statement will thereupon be eligible for sale in the public markets, subject to vesting restrictions, the lock-up agreements described above and Rule 144 limitations applicable to affiliates. See “Executive Compensation—Employee Benefit and Stock Plans” for additional information.

# MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSEQUENCES FOR NON-U.S. HOLDERS OF OUR COMMON STOCK

The following is a general discussion of the material U.S. federal income tax consequences to non-U.S. holders with respect to their ownership and disposition of shares of our common stock purchased in this offering. This discussion is for general information only, is not tax advice, and does not purport to be a complete analysis of all potential tax considerations. Accordingly, all prospective non-U.S. holders of our common stock should consult their tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock. This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, in effect as of the date of this prospectus, all of which are subject to change, possibly with retroactive effect, or to differing interpretation. Any change could alter the tax consequences to non-U.S. holders described in this prospectus. We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment).

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances, nor does it address any aspects of state, local or non-U.S. income taxes or any non-income taxes other than to the limited extent set forth below. This discussion also does not address the potential application of the alternative minimum tax, the Medicare contribution tax on net investment income, or any specific tax consequences that may be relevant to a non-U.S. holder in light of such holder's particular circumstances and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- Insurance companies;
- Tax-exempt organizations or governmental organizations;
- Banks or other financial institutions;
- Brokers or dealers in securities, and traders in securities that use a mark-to-market method of accounting for their securities holdings;
- Partnerships or entities classified as partnerships for U.S. federal income tax purposes and other pass-through entities;
- Tax-qualified retirement plans;
- Persons that own or are deemed to own more than 5% of our capital stock (except to the extent specifically set forth below);
- "Controlled foreign corporations" or "passive foreign investment companies";
- Corporations that accumulate earnings to avoid U.S. federal income tax;
- Owners that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- Persons who acquired our common stock pursuant to the exercise of a stock option or other compensatory transactions;

- Persons subject to special tax accounting rules as a result of any item of gross income with respect to our common stock being taken into account in an “applicable financial statement” (as defined in Section 451(b) of the Code);
- Certain former citizens or long-term residents of the United States; or
- Persons deemed to sell our common stock under the constructive sale provisions of the Code.

In addition, if a partnership or entity classified as a partnership for U.S. federal tax purposes holds our common stock, the tax treatment of a partner generally will depend on the status of the partner, upon the activities of the partnership and upon certain determinations made at the partner level. Accordingly, partnerships that hold our common stock, entities classified as partnerships for U.S. federal income tax purposes and other pass-through entities, as well as partners or members in such entities should consult their tax advisors. There can be no assurance that the Internal Revenue Service (“IRS”) will not challenge one or more of the tax consequences described herein, and we have not obtained, and do not intend to obtain, an opinion of counsel or ruling from the IRS with respect to the U.S. federal income tax consequences to a non-U.S. holder of the purchase, ownership or disposition of our common stock. We urge prospective investors to consult with their tax advisors regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of purchasing, owning and disposing of shares of our common stock.

## Non-U.S. Holder Defined

For purposes of this discussion, except as modified for estate tax purposes, a non-U.S. holder means a beneficial owner of our common stock, other than a partnership or other entity classified as a partnership for U.S. federal income tax purposes, that is not, for U.S. federal income tax purposes:

- An individual who is a citizen or resident of the United States;
- A corporation created or organized in the United States or under the laws of the United States or of any state thereof or the District of Columbia;
- An estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- A trust (x) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust, or (y) which has made a valid election to be treated as a U.S. person.

## Distributions on Our Common Stock

We have never declared or paid, and do not anticipate declaring or paying, any cash dividends on any of our capital stock. However, if we do make distributions on our common stock, those payments generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds both our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder’s capital, and will reduce such holder’s basis in our common stock, but not below zero. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in “—Gain on Sale, Exchange or Other Disposition of Our Common Stock.” Except as otherwise described below in the sections on effectively connected income in the next paragraph, and the sections titled "–Backup Withholding and Information Reporting" and "–Foreign Accounts." Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be provided by an applicable income tax treaty between the United States and such holder’s country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States (and, if an applicable income tax treaty so provides, are also attributable

to a permanent establishment or a fixed base maintained within the United States by such non-U.S. holder) are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to U.S. persons. Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional branch profits tax at a 30% rate or such lower rate as may be provided by an applicable income tax treaty between the United States and such holder's country of residence.

In order to claim the benefit of a tax treaty or to claim exemption from withholding because dividends paid on our common stock are effectively connected with the conduct of a trade or business in the United States, a non-U.S. holder must provide a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E for treaty benefits or IRS Form W-8ECI for effectively connected income, or such successor forms as the IRS designates, prior to the payment of dividends. These forms must be periodically updated. If a non-U.S. holder holds our common stock through a financial institution or other agent acting on such holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. Non-U.S. holders may be eligible to obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

## Gain on Sale, Exchange or Other Disposition of Our Common Stock

Subject to the discussion below regarding backup withholding and foreign accounts, a non-U.S. holder generally will not be subject to any U.S. federal income tax on any gain realized upon such holder's sale, exchange or other disposition of shares of our common stock unless:

- The gain is effectively connected with a U.S. trade or business (and, if an applicable income tax treaty so provides, is also attributable to a permanent establishment or a fixed base maintained within the United States by such non-U.S. holder), in which case the graduated U.S. federal income tax rates applicable to U.S. persons will apply, and, if the non-U.S. holder is a foreign corporation, the additional branch profits tax described above in "—Distributions on Our Common Stock" may also apply;

- The non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the calendar year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax on the net gain derived from the disposition, which may be offset by U.S.-source capital losses of the non-U.S. holder, if any; or

- We are or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter) a "United States real property holding corporation" (a "USRPHC").

We believe that we have not been and are not currently, and we do not anticipate becoming in the future, a USRPHC for U.S. federal income tax purposes, and the remainder of this discussion so assumes. Because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we are or become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, as to which there can be no assurance, a non-U.S. holder will only be subject to tax under these rules if such non-U.S. holder actually or constructively holds more than 5% of such regularly-traded common stock at any time during the shorter of the five-year period preceding such holder's disposition of, or such holder's holding period for, our common stock.

## Federal Estate Tax

Shares of our common stock beneficially owned by an individual who is not a citizen or resident of the United States (as defined for U.S. federal estate tax purposes) at the time of death will generally be included in the decedent's gross estate for U.S. federal estate tax purposes, unless an applicable estate tax treaty provides otherwise.

## Backup Withholding and Information Reporting

Generally, we must report annually to the IRS the amount of dividends paid to each non-U.S. holder, the name and address of such non-U.S. holder, and the amount of tax withheld, if any. A similar report will be sent to each non-U.S. holder. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in such non-U.S. holder's country of residence.

Payments of dividends on or of proceeds from the disposition of our common stock may be subject to additional information reporting and backup withholding at a current rate of 24% unless a non-U.S. holder establishes an exemption, for example, by properly certifying its non-U.S. status on an IRS Form W-8BEN or IRS Form W-8BEN-E or another appropriate version of IRS Form W-8. Notwithstanding the foregoing, backup withholding and information reporting may apply if the applicable withholding agent has actual knowledge, or reason to know, that such holder is a U.S. person.

Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a refund or credit may generally be obtained from the IRS, provided that the required information is furnished to the IRS in a timely manner.

## Foreign Accounts

The Foreign Account Tax Compliance Act, or FATCA, generally imposes a U.S. federal withholding tax of 30% on dividends on and the gross proceeds from a sale or other disposition of our common stock paid to a "foreign financial institution" (as specially defined under these rules), unless otherwise provided by the Treasury Secretary or such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the U.S. account holders of such institution (which include certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise establishes an exemption. FATCA also generally imposes a U.S. federal withholding tax of 30% on dividends on and the gross proceeds from a sale or other disposition of our common stock paid to a "non-financial foreign entity" (as specifically defined for purposes of these rules) unless otherwise provided by the Treasury Secretary or such entity provides the withholding agent with a certification identifying certain substantial direct and indirect U.S. owners of the entity, certifies that there are none or otherwise establishes an exemption. The withholding provisions under FATCA generally apply to dividends on our common stock. The Treasury Secretary has issued proposed regulations providing that the withholding provisions under FATCA do not apply with respect to the gross proceeds from a sale or other disposition of our common stock, which may be relied upon by taxpayers until final regulations are issued. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Prospective investors are encouraged to consult with their tax advisors regarding the possible implications of FATCA on their investment in our common stock.

***Each prospective investor should consult its tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed change in applicable laws.***

# UNDERWRITING

We are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated are acting as joint book-running managers of the offering and as representatives of the underwriters. We and the selling stockholders have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

| Name | Number of Shares |
|---|---|
| J.P. Morgan Securities LLC | 2,460,000 |
| Merrill Lynch, Pierce, Fenner & Smith Incorporated | 2,160,000 |
| BMO Capital Markets Corp. | 690,000 |
| Stifel, Nicolaus & Company, Incorporated | 690,000 |
| Total | 6,000,000 |

The underwriters are committed to purchase all the shares of common stock offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the shares of common stock directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $0.84 per share. After the initial public offering of the shares, if all of the shares of common stock are not sold at the initial public offering price, the underwriters may change the offering price and other selling terms. Sales of shares of common stock made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to 900,000 additional shares of common stock from the selling stockholders. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us and the selling stockholders per share of common stock. The underwriting fee is $1.40 per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by us and the selling stockholders assuming both no exercise and full exercise of the underwriters' option to purchase additional shares from the selling stockholders.

| | Paid by the Company | | Paid by the selling stockholders | |
|---|---|---|---|---|
| | Without Option | With Full Option Exercise | Without Option | With Full Option Exercise |
| Per Share | $ 1.40 | $ 1.40 | $ — | $ 1.40 |
| Total | $ 8,400,000 | $ 8,400,000 | $ — | $ 1,260,000 |

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately $2.8 million. We have agreed to reimburse the underwriters for certain expenses incurred in connection with, among others, the review and clearance by the Financial Industry Regulatory Authority, Inc. in an amount of up to $40,000. In addition, the underwriters have agreed to reimburse us for certain of the expenses incurred by us in connection with this offering.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that, subject to certain exceptions, we will not (i) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise dispose of, directly or indirectly, or file with the SEC a registration statement under the Securities Act relating to, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing, or (ii) enter into any swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any shares of common stock or any such other securities (regardless of whether any of these transactions are to be settled by the delivery of shares of common stock or such other securities, in cash or otherwise), in each case without the prior written consent of J.P. Morgan Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated for a period of 180 days after the date of this prospectus, other than the shares of our common stock to be sold hereunder and any shares of our common stock issued upon the exercise of options granted under our existing stock-based compensation plans.

Our directors, executive officers and substantially all of our holders of our common stock and securities convertible into or exercisable or exchangeable for shares of our common stock have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each of these persons or entities, with certain exceptions, for a period of 180 days after the date of this prospectus, may not, without the prior written consent of J.P. Morgan Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated, (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (including, without limitation, common stock or such other securities which may be deemed to be beneficially owned by such

directors, executive officers and holders in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant), (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the common stock or such other securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of common stock or such other securities, in cash or otherwise, or (3) make any demand for or exercise any right with respect to the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

Our common stock has been approved for quotation on The Nasdaq Stock Market under the symbol "SILK."

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of the common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be "covered" shorts, which are short positions in an amount not greater than the underwriters' option to purchase additional shares referred to above, or may be "naked" shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act of 1933, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on The Nasdaq Stock Market, in the over the counter market or otherwise.

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters considered a number of factors including:

- The information set forth in this prospectus and otherwise available to the representatives;
- Our prospects and the history and prospects for the industry in which we compete;

- An assessment of our management;
- Our prospects for future earnings;
- The general condition of the securities markets at the time of this offering;
- The recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- Other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for shares of our common stock, or that the shares will trade in the public market at or above the initial public offering price.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction.

Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

## Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State"), with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, no offer of shares may be made to the public in that Relevant Member State other than:

A. to any legal entity which is a qualified investor as defined in the Prospectus Directive;

B. to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), subject to obtaining the prior consent of the underwriters; or

C. in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and us that it is a "qualified investor" within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive.

In the case of any shares being offered to a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Relevant Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer of shares to the public" in relation to any shares in any Relevant Member State means the communication in any form and by means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (as amended, including by Directive 2010/73/EU), and includes any relevant implementing measure in the Relevant Member State.

We, the representatives and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

This prospectus has been prepared on the basis that any offer of shares in any Relevant Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of shares. Accordingly any person making or intending to make an offer in that Relevant Member State of shares which are the subject of the offering contemplated in this prospectus may only do so in circumstances in which no obligation arises for us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither we nor the underwriters have authorized, nor do they authorize, the making of any offer of shares in circumstances in which an obligation arises for us or the underwriters to publish a prospectus for such offer.

## Notice to Prospective Investors in the United Kingdom

This document is only being distributed only to, and is only directed at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons") or otherwise in circumstances which have not resulted and will not result in an offer to the public of the shares in the United Kingdom within the meaning of the Financial Services and Markets Act 2000.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

## Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). The investor

protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

## Notice to Prospective Investors in the Dubai International Financial Centre

This document relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority ("DFSA"). This document is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus supplement nor taken steps to verify the information set forth herein and has no responsibility for this document. The securities to which this document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this document you should consult an authorized financial advisor.

In relation to its use in the DIFC, this document is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

## Notice to Prospective Investors in Australia

No prospectus or other disclosure document (as defined in the Corporations Act 2001 (Cth) of Australia, or Corporations Act) in relation to the shares of common stock has been or will be lodged with the Australian Securities & Investments Commission, or ASIC. This document has not been lodged with ASIC and is only directed to certain categories of exempt persons. Accordingly, if you receive this document in Australia: (a) you confirm and warrant that you are either: (i) a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act; (ii) a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to us which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made; (iii) a person associated with the company under section 708(12) of the Corporations Act; or (iv) a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act, and to the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this document is void and incapable of acceptance; and (b) you warrant and agree that you will not offer any of the shares of common stock for resale in Australia within 12 months of the shares of common stock being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

## Notice to Prospective Investors in Hong Kong

The shares of common stock may not be offered or sold in Hong Kong by means of any document other than (a) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), (b) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder; or (c) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong). No advertisement, invitation or document relating to the shares of common stock may be issued or may be in the possession of any person for the purposes of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares of common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

## Notice to Prospective Investors in Japan

The shares of common stock have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in or into Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of any Japanese Person, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time. For the purposes of this paragraph, "Japanese Person" shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

## Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares of common stock may not be circulated or distributed, nor may the shares of common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

Securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

(a) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(b) where no consideration is or will be given for the transfer;

(c) where the transfer is by operation of law;

(d) as specified in Section 276(7) of the SFA; or

(e) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

## Notice to Prospective Investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103

Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

## Other Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities.

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of the Company. The underwriters and their respective affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

# LEGAL MATTERS

Wilson Sonsini Goodrich & Rosati, P.C., Palo Alto, California will pass upon the validity of the shares of common stock offered by this prospectus. Certain members of, and investment partnerships comprised of members of, and persons associated with, Wilson Sonsini Goodrich & Rosati, P.C. own an interest representing less than one percent of the shares of our common stock. Latham & Watkins LLP, Costa Mesa, California is acting as counsel for the underwriters.

# EXPERTS

The consolidated financial statements as of December 31, 2017 and 2018 and for the years ended December 31, 2017 and 2018 included in this prospectus have been so included in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

# WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not include all of the information contained in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. You should refer to the registration statement and its exhibits for additional information. Whenever we make references in this prospectus to any of our contracts, agreements or other documents, such references are not necessarily complete and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

You can read our SEC filings, including the registration statement and its exhibits, over the Internet at the SEC's web site at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, N.E., Washington, DC 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

When we complete this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file annual, quarterly and special reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above. We also maintain a website at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained on our website is not a part of this prospectus.

# Silk Road Medical, Inc.
## Index to Consolidated Financial Statements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## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Silk Road Medical, Inc.

***Opinion on the Financial Statements***

We have audited the accompanying consolidated balance sheets of Silk Road Medical, Inc. and its subsidiaries (the "Company") as of December 31, 2018 and December 31, 2017, and the related consolidated statement of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders' deficit and of cash flows, for each of the two years in the period ended December 31, 2018, including the related notes and financial statement schedule listed in the index appearing under Item 16 (b) (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and December 31, 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018 in conformity with accounting principles generally accepted in the United States of America.

*Substantial Doubt About the Company's Ability to Continue as a Going Concern*

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plan in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustment that might result from the outcome of this uncertainty.

***Basis for Opinion***

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Jose, California
March 1, 2019, except for the effects of the reverse stock split described in Note 1, as to which the date is March 27, 2019

We have served as the Company's auditor since 2013.

# Silk Road Medical, Inc.
## Consolidated Balance Sheets

| *(in thousands, except share and per share data)* | December 31, 2017 | December 31, 2018 | December 31, 2018 Proforma |
|---|---|---|---|
| | | | (unaudited) |
| **Assets** | | | |
| Current assets: | | | |
| Cash and cash equivalents | $ 33,331 | $ 24,990 | |
| Accounts receivable, net of allowances of $611 and $1,885 at December 31, 2017 and 2018, respectively | 5,215 | 4,520 | |
| Inventories | 3,248 | 5,744 | |
| Prepaid expenses and other current assets | 279 | 1,408 | |
| Total current assets | 42,073 | 36,662 | |
| Property and equipment, net | 486 | 2,880 | |
| Restricted cash | 510 | 310 | |
| Other non-current assets | 17 | 1,029 | |
| Total assets | $ 43,086 | $ 40,881 | |
| **Liabilities, redeemable convertible preferred stock and stockholders' deficit** | | | |
| Current liabilities: | | | |
| Accounts payable | $ 1,546 | $ 1,252 | |
| Accrued liabilities | 3,109 | 7,586 | |
| Total current liabilities | 4,655 | 8,838 | |
| Long-term debt | 27,589 | 44,201 | |
| Redeemable convertible preferred stock warrant liability | 4,185 | 16,091 | $ — |
| Other liabilities | — | 1,069 | |
| Total liabilities | 36,429 | 70,199 | |
| Commitments and contingencies (Note 7) | | | |
| Redeemable convertible preferred stock issuable in series, $0.001 par value | | | |
| Shares authorized: 24,069,615 at December 31, 2017 and 2018, actual | | | |
| Shares issued and outstanding: 21,233,190 at December 31, 2017 and 2018, actual, none pro forma (unaudited) | | | |
| Liquidation preference: $121,144 at December 31, 2017 and 2018 | 105,235 | 105,235 | — |
| Stockholders' deficit: | | | |
| Common stock, $0.001 par value | | | |
| Shares authorized: 29,879,220 at December 31, 2017 and 2018, actual | | | |
| Shares issued and outstanding: 663,270 and 1,135,310 at December 31, 2017 and 2018, respectively, actual, 24,228,959 pro forma (unaudited) | 1 | 1 | 24 |
| Additional paid-in capital | 2,977 | 4,557 | 125,860 |
| Accumulated deficit | (101,556) | (139,111) | (139,111) |
| Total stockholders' deficit | (98,578) | (134,553) | $ (13,227) |
| Total liabilities and stockholders' deficit | $ 43,086 | $ 40,881 | |

The accompanying notes are an integral part of these consolidated financial statements.

# Silk Road Medical, Inc.
## Consolidated Statements of Operations and Comprehensive Loss

| *(in thousands, except share and per share data)* | Year Ended December 31, | |
|---|---|---|
| | 2017 | 2018 |
| Revenue | $ 14,258 | $ 34,557 |
| Cost of goods sold | 5,129 | 10,874 |
| Gross profit | 9,129 | 23,683 |
| Operating expenses: | | |
| Research and development | 7,242 | 10,258 |
| Selling, general and administrative | 20,261 | 34,820 |
| Total operating expenses | 27,503 | 45,078 |
| Loss from operations | (18,374) | (21,395) |
| Interest income | 34 | 189 |
| Interest expense | (3,943) | (4,361) |
| Other income (expense), net | 2,927 | (12,063) |
| Net loss and comprehensive loss | (19,356) | (37,630) |
| Net loss and comprehensive loss attributable to non-controlling interest | — | 1 |
| Net loss and comprehensive loss attributable to Silk Road Medical, Inc. common stockholders | $ (19,356) | $ (37,629) |
| Net loss per share attributable to Silk Road Medical, Inc. common stockholders, basic and diluted | $ (44.58) | $ (39.16) |
| Weighted average common shares used to compute net loss per share attributable to Silk Road Medical, Inc. common stockholders, basic and diluted | 434,158 | 960,882 |
| Pro forma net loss per share attributable to Silk Road Medical, Inc. common stockholders, basic and diluted (unaudited) | | $ (1.07) |
| Pro forma weighted average common shares used to compute net loss per share attributable to Silk Road Medical, Inc. common stockholders, basic and diluted (unaudited) | | 24,050,299 |

The accompanying notes are an integral part of these consolidated financial statements.

# Silk Road Medical, Inc.
## Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit

| *(in thousands, except share data)* | Redeemable Convertible Preferred Stock | | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Non-controlling Interest | Total |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | | |
| **Balances at December 31, 2016** | 14,350,216 | $ 63,417 | 372,632 | $ 1 | $ 2,104 | $ (82,200) | $ — | $ (80,095) |
| Issuance of Series C convertible preferred stock, net of issuance costs | 6,882,974 | 41,818 | — | — | — | — | — | — |
| Exercise of stock options | — | — | 290,638 | — | 338 | — | — | 338 |
| Employee stock-based compensation | — | — | — | — | 442 | — | — | 442 |
| Nonemployee stock-based compensation | — | — | — | — | 93 | — | — | 93 |
| NeuroCo common stock issuance | — | — | — | — | — | — | — | — |
| Net loss and comprehensive loss | — | — | — | — | — | (19,356) | — | (19,356) |
| **Balances at December 31, 2017** | 21,233,190 | 105,235 | 663,270 | 1 | 2,977 | (101,556) | — | (98,578) |
| Exercise of stock options | — | — | 438,578 | — | 656 | — | — | 656 |
| Employee stock-based compensation | — | — | — | — | 728 | — | — | 728 |
| Nonemployee stock-based compensation | — | — | — | — | 183 | — | — | 183 |
| NeuroCo common stock issuance | — | — | — | — | — | — | 1 | 1 |
| Issuance of common stock in connection with NeuroCo merger | — | — | 33,462 | — | — | — | — | — |
| Cumulative effect of change in accounting principle - ASC 606 adoption | — | — | — | — | — | 87 | — | 87 |
| Cumulative effect of change in accounting treatment - ASU 2016-09 | — | — | — | — | 13 | (13) | — | — |
| Net loss and comprehensive loss | — | — | — | — | — | (37,629) | (1) | (37,630) |
| **Balances at December 31, 2018** | 21,233,190 | $ 105,235 | 1,135,310 | $ 1 | $ 4,557 | $ (139,111) | $ — | $ (134,553) |

The accompanying notes are an integral part of these consolidated financial statements.

# Silk Road Medical, Inc.
## Consolidated Statements of Cash Flows

| *(in thousands)* | Year Ended December 31, 2017 | 2018 |
|---|---|---|
| **Cash flows from operating activities** | | |
| Net loss | $ (19,356) | $ (37,630) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization expense | 129 | 517 |
| Stock-based compensation expense | 535 | 911 |
| Change in fair value of redeemable convertible preferred stock warrant liability | (2,958) | 11,906 |
| Amortization of debt discount and debt issuance costs | 89 | 68 |
| Non-cash interest expense | 1,705 | 1,555 |
| Loss on disposal of property and equipment | — | 159 |
| Provision for accounts receivable allowances | 423 | 1,835 |
| Provision for excess and obsolete inventories | 63 | 23 |
| Changes in assets and liabilities | | |
| Accounts receivable | (4,793) | (1,003) |
| Inventories | (2,408) | (2,565) |
| Prepaid expenses and other current assets | (10) | (1,128) |
| Other assets | — | (62) |
| Accounts payable | 678 | (309) |
| Accrued liabilities | 651 | 3,622 |
| Other liabilities | — | 406 |
| Net cash used in operating activities | (25,252) | (21,695) |
| **Cash flows from investing activities** | | |
| Purchase of property and equipment | (443) | (2,276) |
| Proceeds from sale of property and equipment | — | 6 |
| Net cash used in investing activities | (443) | (2,270) |
| **Cash flows from financing activities** | | |
| Proceeds from long-term debt | 5,000 | 15,000 |
| Proceeds from issuance of common stock | 338 | 656 |
| Payments of deferred offering costs | — | (233) |
| Non-controlling interest | — | 1 |
| Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs | 41,818 | — |
| Net cash provided by financing activities | 47,156 | 15,424 |
| **Net change in cash, cash equivalents and restricted cash** | 21,461 | (8,541) |
| **Cash, cash equivalents and restricted cash, beginning of year** | 12,380 | 33,841 |
| **Cash, cash equivalents and restricted cash, end of year** | $ 33,841 | $ 25,300 |
| **Supplemental disclosure of cash flow information** | | |
| Cash paid for interest | $ 2,149 | $ 2,738 |
| Non-cash investing and financing activities: | | |
| Accounts payable and accrued liabilities for purchases of property and equipment | $ 14 | $ 6 |
| Landlord paid tenant improvements | $ — | $ 794 |
| Unpaid deferred offering costs | $ — | $ 717 |

The accompanying notes are an integral part of these consolidated financial statements.

## 1. Formation and Business of the Company

### The Company

Silk Road Medical, Inc. (the "Company") was incorporated in the state of Delaware on March 21, 2007. The Company has developed a technologically advanced, minimally-invasive solution for patients with carotid artery disease who are at risk for stroke. The Company's portfolio of TCAR products enable a new procedure, referred to as transcarotid artery revascularization, or TCAR, that combines the benefits of endovascular techniques and surgical principles. The Company's manufactures and sells in the United States its portfolio of TCAR products which are designed to provide direct access to the carotid artery, effective reduction in stroke risk throughout the procedure, and long-term restraint of carotid plaque. The Company commercialized its products in the United States in April 2016.

### Liquidity and Going Concern

In the course of its activities, the Company has incurred losses and negative cash flows from operations since its inception. As of December 31, 2018, the Company had an accumulated deficit of $139,111,000. The Company expects to incur losses for the foreseeable future. The Company does not believe that its cash and cash equivalents of $24,990,000 at December 31, 2018, as well as its expected revenues and additional borrowings available under the loan agreement with CRG Partners III L.P. and certain of its affiliated funds (collectively "CRG") will provide sufficient funds to allow the Company to fund its planned current operations for the next twelve months from the issuance of these consolidated financial statements.

The Company expects to seek additional funding in the form of debt or equity financings to make strategic investments in its business; however, there can be no assurance that such efforts will be successful or that, in the event that they are successful, the terms and conditions of such financing will be favorable. If the Company's revenue levels from its products are not sufficient or if the Company is unable to secure additional funding when desired, the Company may need to delay the development, commercialization and marketing of its products and scale back its business and operations.

The Company has concluded that there is substantial doubt about its ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

### Reverse Stock Split

On March 13, 2019, the Company's Board of Directors approved an amendment to the Company's amended and restated certificate of incorporation to effect a 1-for-2.7 reverse stock split of the Company's common stock and redeemable convertible preferred stock to be consummated prior to the effectiveness of the Company's planned initial public offering ("IPO"). The par values of the common stock and redeemable convertible preferred stock were not adjusted as a result of the reverse stock split. Accordingly, all common stock, redeemable convertible preferred stock, stock options and warrants, and related per share amounts in the consolidated financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split. The reverse stock split was effected on March 27, 2019.

## 2. Summary of Significant Accounting Policies

### Basis of Preparation

The accompanying consolidated financial statements have been prepared in accordance with the accounting principles generally accepted in the United States of America ("U.S. GAAP"). The consolidated financial statements include the accounts of the Company and its consolidated subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

### Principles of Consolidation

As of December 31, 2017, the consolidated financial statements of the Company include the accounts of Silk Road Medical, Inc. and its consolidated variable interest entity ("VIE"). Disclosure regarding the Company's participation in the VIE is included in Note 12, "Variable Interest Entity – NeuroCo". On December 17, 2018, the Company acquired all assets and assumed all liabilities of its VIE. All intercompany balances and transactions have been eliminated in consolidation.

### Variable Interest Entity

As of December 31, 2017, the Company had an interest in a VIE. Determining whether to consolidate a VIE requires judgment in assessing (i) whether an entity is a VIE and (ii) if the Company is the entity's primary beneficiary and thus required to consolidate the entity. To determine if the Company is the primary beneficiary of a VIE, the Company evaluates whether it has (i) the power to direct the activities that most significantly impact the VIE's economic performance and (ii) the obligation to absorb losses or the right to receive benefits of the VIE that could potentially be significant to the VIE. The Company's evaluation includes identification of significant activities and an assessment of its ability to direct those activities.

### Unaudited Pro Forma Balance Sheet Information

The unaudited pro forma consolidated balance sheet as of December 31, 2018 reflects: (i) the conversion of all outstanding shares of redeemable convertible preferred stock into shares of common stock immediately prior to the completion of the Company's planned IPO, following receipt of the requisite approval of preferred stockholders; (ii) the automatic net exercise of the redeemable convertible preferred stock warrants into shares of common stock, based on an initial public offering price of $20.00 per share, and the related reclassification of the redeemable convertible warrant liability to common stock and additional paid-in-capital; and (iii) the automatic net exercise of the common stock warrants into shares of common stock, based on an initial public offering price of $20.00 per share. Shares of common stock contemplated to be sold in the Company's planned IPO and related net proceeds are excluded from the pro forma information.

### Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements. Management uses significant judgment when making estimates related to the common stock valuation and related stock-based compensation, the valuation of the redeemable convertible preferred stock warrants, the valuation of deferred tax assets, provisions for doubtful accounts receivable and excess and obsolete inventories, clinical trial accruals, and the reserves for sales returns. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

**Fair Value of Financial Instruments**

The Company has evaluated the estimated fair value of its financial instruments as of December 31, 2017 and 2018. The carrying amounts of cash equivalents, restricted cash, accounts receivable, accounts payable and accrued liabilities approximate their respective fair values because of the short-term nature of these instruments. Management believes that its borrowings bear interest at the prevailing market rates for instruments with similar characteristics; accordingly, the carrying value of this instrument approximates its fair value. Fair value accounting is applied to the redeemable convertible preferred stock warrant liability.

**Cash, Cash Equivalents and Restricted Cash**

The Company considers all highly liquid investments with an original maturity of three months or less at the time of purchase to be cash equivalents. Cash equivalents are considered available-for-sale marketable securities and are recorded at fair value, based on quoted market prices. As of December 31, 2017 and 2018, the Company's cash equivalents are entirely comprised of investments in money market funds.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same amounts shown in the consolidated statements of cash flows (in thousands):

| | December 31, | |
|---|---|---|
| | 2017 | 2018 |
| Cash and cash equivalents | $ 33,331 | $ 24,990 |
| Restricted cash | 510 | 310 |
| Total cash, cash equivalents and restricted cash | $ 33,841 | $ 25,300 |

Restricted cash as of December 31, 2017 and 2018 consists of a letter of credit of $310,000 representing collateral for the Company's facility lease. As of December 31, 2017, restricted cash additionally included a certificate of deposit of $200,000 associated with the Company's corporate credit cards.

**Concentration of Credit Risk, and Other Risks and Uncertainties**

Financial instruments that potentially subject the Company to credit risk consist of cash and cash equivalents and accounts receivable to the extent of the amounts recorded on the consolidated balance sheet.

The Company's policy is to invest in money market funds, which are classified as cash equivalents on the consolidated balance sheet. The Company's cash are held in Company accounts at two financial institutions and such amounts may exceed federally insured limits. The Company's money market funds are invested in highly rated money market funds.

The Company provides for uncollectible amounts when specific credit problems are identified. In doing so, the Company analyzes historical bad debt trends, customer credit worthiness, current economic trends and changes in customer payment patterns when evaluating the adequacy of the allowance for doubtful accounts.

The Company's accounts receivable are due from a variety of health care organizations in the United States. At December 31, 2017 and 2018, no customer represented 10% or more of the Company's accounts receivable. For the years ended December 31, 2017 and 2018, there were no customers that represented 10% or more of revenue.

The Company manufactures certain of its commercial products in-house. Certain of the Company's product components and sub-assemblies continue to be manufactured by sole suppliers, the most significant of which is the ENROUTE stent. Disruption in component or sub-assembly supply from these manufacturers or from in-house production would have a negative impact on the Company's financial position and results of operations.

The Company is subject to certain risks, including that its devices may not be approved or cleared for marketing by governmental authorities or be successfully marketed. There can be no assurance that the Company's products will achieve widespread adoption in the marketplace, nor can there be any assurance that existing devices or any future devices can be developed or manufactured at an acceptable cost and with appropriate performance characteristics. The Company is also subject to risks common to companies in the medical device industry, including, but not limited to, new technological innovations, dependence upon third-party payers to provide adequate coverage and reimbursement, dependence on key personnel and suppliers, protection of proprietary technology, product liability claims, and compliance with government regulations.

Existing or future devices developed by the Company may require approvals or clearances from the FDA or international regulatory agencies. In addition, in order to continue the Company's operations, compliance with various federal and state laws is required. If the Company were denied or delayed in receiving such approvals or clearances, it may be necessary to adjust operations to align with the Company's currently approved portfolio. If clearance for the products in the current portfolio were withdrawn by the FDA, this would have a material adverse impact on the Company.

**Accounts Receivable**

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The Company estimates allowances for doubtful accounts and for product returns. Specifically, the Company makes estimates on the collectability of customer accounts and sales returns and allowances based primarily on analysis of historical trends and experience and changes in customers' financial condition. The Company uses its judgment, based on the best available facts and circumstances, and records an allowance against amounts due to reduce the receivable to the amount that is expected to be collected. These specific allowances are reevaluated and adjusted as additional information is received that impacts the amount reserved. To date, the Company has not experienced material credit-related losses.

**Inventories**

Inventories are valued at the lower of cost to purchase or manufacture the inventory or net realizable value. Cost is determined using the first-in, first-out method for all inventories. Net realizable value is determined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The Company regularly reviews inventory quantities in consideration of actual loss experiences, projected future demand, and remaining shelf life to record a provision for excess and obsolete inventory when appropriate. The Company's policy is to write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected lower of cost or net realizable value, and inventory in excess of expected requirements. The estimate of excess quantities is judgmental and primarily dependent on the Company's estimates of future demand for a particular product. If the estimate of future demand is too high, the Company may have to increase the reserve for excess inventory for that product and record a charge to the cost of goods sold.

**Property and Equipment**

Property and equipment are recorded at cost less accumulated depreciation or amortization. Repairs and maintenance costs are expensed as incurred. Depreciation and amortization are calculated using the straight-line method over the estimated useful lives of the assets, typically three to five years. Leasehold improvements are amortized using the straight-line method over the shorter of the lease term or

estimated useful economic life of the asset. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in operations in the period realized.

**Deferred Initial Public Offering Costs**

Specific incremental legal, accounting and other fees and costs directly attributable to a proposed or actual offering of securities may properly be deferred and charged against the gross proceeds of the offering. In the event the Company's planned IPO does not occur or is significantly delayed, all of the costs will be expensed. As of December 31, 2018, there were $950,000 of offering costs primarily consisting of legal and accounting fees that were capitalized in other non-current assets on the consolidated balance sheet. No deferred offering costs were capitalized as of December 31, 2017.

**Impairment of Long-Lived Assets**

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. If indicators of impairment exist, an impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the assets and their eventual disposition are less than their carrying amount. Impairment, if any, is measured as the amount by which the carrying amount of the long-lived assets exceeds their fair value. The Company did not record any impairment of long-lived assets for the years ended December 31, 2017 and 2018.

**Redeemable Convertible Preferred Stock Warrant Liability**

The Company accounts for its warrants for shares of redeemable convertible preferred stock as a liability based upon the characteristics and provisions of each instrument. Redeemable convertible preferred stock warrants classified as a liability are initially recorded at their fair value on the date of issuance and are subject to remeasurement at each subsequent balance sheet date. Any change in fair value as a result of a remeasurement is recognized as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss.

**Redeemable Convertible Preferred Stock**

The Company records its redeemable convertible preferred stock at fair value on the dates of issuance, net of issuance costs. A redemption event will only occur upon the liquidation or winding up of the Company, a greater than 50% change in control, or sale of substantially all of the assets of the Company. In the event of a change of control of the Company, proceeds received from the sale of such shares will be distributed in accordance with the liquidation preferences set forth in the Company’s amended and restated certificate of incorporation unless the holders of redeemable convertible preferred stock otherwise agree or have converted their shares into shares of common stock. Therefore, redeemable convertible preferred stock is classified outside of stockholders’ deficit on the balance sheet as events triggering the liquidation preferences are not solely within the Company’s control. The Company is not required to adjust the carrying values of the redeemable convertible preferred stock to the redemption value of such shares since it is uncertain whether or when a redemption event will occur. Subsequent adjustments to increase the carrying values to the redemption values will be made only when it becomes probable that such redemption will occur.

**Revenue Recognition**

On January 1, 2018, the Company adopted Accounting Standards Codification (“ASC”) Topic 606, "Revenue from Contracts with Customers," using the modified retrospective method applied to contracts which were not completed as of that date. Revenue for the year ended December 31, 2018 is presented under ASC 606, while prior period revenue amounts are not adjusted and continue to be

reported in accordance with the Company's historic accounting under ASC 605, "Revenue Recognition." Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the entity satisfies a performance obligation.

Under ASC 606, assuming all other revenue recognition criteria have been met, the Company will recognize revenue earlier for arrangements where the Company has satisfied its performance obligations but have not issued invoices. As of December 31, 2018, the Company recorded $128,000 of unbilled receivables, which are included in accounts receivable, net on the consolidated balance sheet, as the Company has an unconditional right to payment as of the end of the applicable period.

The Company recognized the cumulative effect of initially applying ASC 606 as an adjustment to the opening balance of accumulated deficit. The cumulative effect of the changes made to the consolidated balance sheet as of January 1, 2018 for the adoption of ASC 606 were as follows (in thousands):

| | Balance at December 31, 2017 | Adjustments Due to ASC 606 | Balance at January 1, 2018 |
|---|---|---|---|
| Accounts receivable, net | $ 5,215 | $ 136 | $ 5,351 |
| Inventories | 3,248 | (46) | 3,202 |
| Accrued liabilities | 3,109 | 4 | 3,113 |
| Accumulated deficit | (101,556) | 87 | (101,469) |

In accordance with ASC 606, the disclosure of the impact of adoption on the consolidated balance sheet and statement of operations and comprehensive loss were as follows (in thousands):

| | Year Ended December 31, 2018 | | |
|---|---|---|---|
| | Balance As Reported | Balance Before ASC 606 Adoption | Effect of Change |
| **Balance sheet:** | | | |
| Accounts receivable, net | $ 4,520 | $ 4,494 | $ 26 |
| Inventories | 5,744 | 5,766 | (22) |
| Accrued liabilities | 7,586 | 7,586 | — |
| Accumulated deficit | (139,111) | (139,107) | (4) |
| **Statement of operations and comprehensive loss:** | | | |
| Revenue | 34,557 | 34,583 | (26) |
| Cost of goods sold | 10,874 | 10,852 | 22 |

The Company's revenue is generated from the sale of its products to hospitals and medical centers in the United States through direct sales representatives. Revenue is recognized when obligations under the terms of a contract with customers are satisfied, which occurs with the transfer of control of the Company's products to its customers, either upon shipment of the product or delivery of the product to the customer under the Company's standard terms and conditions. The Company's products are readily available for usage as soon as the customer possesses it. Upon receipt, the customer controls the economic benefits of the product, has significant risks and rewards, and the legal title. The Company has present right to payment; therefore, the transfer of control is deemed to happen at a point in time. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring the goods.

For sales where the Company's sales representative hand delivers product directly to the hospital or medical center from the sales representative's trunk stock inventory, the Company recognizes revenue upon delivery, which represents the point in time when control transfers to the customer. Upon delivery there are legally-enforceable rights and obligations between the parties which can be identified, commercial substance exists and collectibility is probable. For sales which are sent directly from the Company to hospitals and medical centers, the transfer of control occurs at the time of shipment or delivery of the product. There are no further performance obligations by the Company or the sales representative to the customer after delivery under either method of sale. As allowed under the practical expedient, the Company does not disclose the value of unsatisfied performance obligations for (i) contracts with an original expected length of one year or less and (ii) contracts for which it recognizes revenue at the amount to which it has the right to invoice for services performed.

The Company is entitled to the total consideration for the products ordered by customers as product pricing is fixed according to the terms of customer contracts and payment terms are short. Payment terms fall within the one-year guidance for the practical expedient which allows the Company to forgo adjustment of the promised amount of consideration for the effects of a significant financing component. The Company excludes taxes assessed by governmental authorities on revenue-producing transactions from the measurement of the transaction price.

Costs associated with product sales include commissions and royalties. The Company applies the practical expedient and recognizes commissions and royalties as expense when incurred because the expense is incurred at a point in time and the amortization period is less than one year. Commissions are recorded as selling expense and royalties are recorded as cost of revenue in the consolidated statements of operations and comprehensive loss.

The Company accepts product returns at its discretion or if the product is defective as manufactured. The Company establishes estimated provisions for returns based on historical experience. The Company elected to expense shipping and handling costs as incurred and includes them in the cost of goods sold. In those cases where the Company bills shipping and handling costs to customers, it will classify the amounts billed as a component of revenue.

As noted, revenue for the year ended December 31, 2018 is presented under ASC 606, while prior period revenue amounts are not adjusted and continue to be reported in accordance with the Company's historic accounting under ASC 605, "Revenue Recognition." Under ASC 605, the Company recognized revenue when all of the following criteria were met:

- persuasive evidence of an arrangement exists;
- the sales price is fixed or determinable;
- collection of the relevant receivable is reasonably assured at the time of sale; and
- delivery has occurred or services have been rendered.

The Company recognized revenue when title to the goods and risk of loss transferred to the customer, which was upon shipment of the product under the Company's standard terms and conditions. The Company estimated reductions in revenue for potential returns of products by customers. In making such estimates, management analyzed historical returns, current economic trends and changes in customer demand and acceptance of its products. The Company expensed shipping and handling costs as incurred and included them in the cost of goods sold. In those cases where the Company billed shipping and handling costs to customers, it would classify the amounts billed as a component of revenue.

**Cost of Goods Sold**

The Company manufactures certain of its portfolio of TCAR products at its facility and purchases other products from third party manufacturers. Cost of goods sold consists primarily of costs related to materials, components and subassemblies, manufacturing overhead costs, direct labor, reserves for excess, obsolete and non-sellable inventories as well as distribution-related expenses. A significant portion of the Company's cost of goods sold currently consists of manufacturing overhead costs. These overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. Cost of goods sold also includes depreciation expense for production equipment and certain direct costs such as shipping costs and royalties.

**Research and Development**

The Company expenses research and development costs as incurred. Research and development expenses consist primarily of engineering, product development, clinical studies to develop and support the Company's products, regulatory expenses, medical affairs and other costs associated with products and technologies that are in development. Research and development expenses include employee compensation, including stock-based compensation, supplies, consulting, prototyping, testing, materials, travel expenses, depreciation and an allocation of facility overhead expenses. Additionally, research and development expenses include costs associated with our clinical studies including clinical trial design, clinical site reimbursement, data management, travel expenses and the cost of products used for clinical trials and internal and external costs associated with the Company's regulatory compliance and quality assurance functions, including the costs of outside consultants and contractors that assist in the process of submitting and maintaining regulatory filings, and overhead costs.

**Clinical Trials**

The Company accrues and expenses costs for its clinical trial activities performed by third parties, including clinical research organizations and other service providers, based upon estimates of the work completed over the life of the individual study in accordance with associated agreements. The Company determines these estimates through discussion with internal personnel and outside service providers as to progress or stage of completion of trials or services pursuant to contracts with clinical research organizations and other service providers and the agreed-upon fee to be paid for such services.

**Advertising Costs**

The Company expenses advertising costs as incurred. Advertising costs include design and production costs, including website development, physician and patient testimonial videos, written media campaigns, and other items. Advertising costs of $218,000 and $186,000 were expensed during the years ended December 31, 2017 and 2018, respectively.

**Foreign Currency**

The Company records net gains and losses resulting from foreign exchange transactions as a component of foreign currency exchange gains or losses in other income (expense), net. The Company had no

material foreign currency exchange gains or losses during the years ended December 31, 2017 and 2018.

**Stock–Based Compensation**

The Company accounts for stock-based compensation in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 718, "Compensation-Stock Compensation." ASC 718 requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based payments including stock options. ASC 718 requires companies to estimate the fair value of all share-based payment option awards on the date of grant using an option pricing model. The fair value of stock options is recognized over the period during which an optionee is required to provide services in exchange for the option award, known as the requisite service period (usually the vesting period), on a straight-line basis. For performance-based stock options, the Company will assess the probability of performance conditions being achieved in each reporting period. The amount of stock-based compensation expense recognized in any one period related to performance-based stock options can vary based on the achievement or anticipated achievement of the performance conditions.

In March 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-09, "Stock Compensation (Topic 718): Improvements to Employee Shared-Based Payment Accounting." Under ASU 2016-09, entities are permitted to make an accounting policy election to either estimate forfeitures on share-based payment awards, as previously required, or to recognize forfeitures as they occur. The Company made an accounting policy election to account for forfeitures as they occur. This change has been applied on a modified retrospective basis, resulting in a cumulative-effect adjustment to increase accumulated deficit by $13,000 as of January 1, 2018, the date of adoption.

Prior to January 1, 2018, the Company accounted for equity instruments issued to nonemployees in accordance with ASC 505-50 "Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods or Services." Equity instruments issued to nonemployees were recorded at their fair value on the measurement date and were subject to periodic adjustments as the underlying equity instruments vest. The Company believed that the fair value of the equity instrument was more reliably measured than the fair value of the services received.

**Income Taxes**

The Company accounts for income taxes under the liability method, whereby deferred tax assets and liabilities are determined based on the difference between the consolidated financial statements and tax bases of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to affect taxable income. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company also follows the provisions of ASC 740-10, "Accounting for Uncertainty in Income Taxes." ASC 740-10 prescribes a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or expected to be taken on a tax return. No liability related to uncertain tax positions is recorded on the consolidated financial statements. It is the Company's policy to include penalties and interest expense related to income taxes as part of the provision for income taxes.

**Net Loss per Share Attributable to Common Stockholders**

Basic net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration for potential dilutive common shares. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common

stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, redeemable convertible preferred stock and warrants, and common stock options are considered to be potentially dilutive securities. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share as the inclusion of all potential dilutive common shares would have been anti-dilutive.

The Company allocates no loss to participating securities because they have no contractual obligation to share in the losses of the Company. The shares of the Company's redeemable convertible preferred stock participate in any dividends declared by the Company and are therefore considered to be participating securities.

Net loss per share was determined as follows (in thousands, except share and per share data):

| | Year Ended December 31, | |
|---|---|---|
| | 2017 | 2018 |
| Net loss attributable to Silk Road Medical, Inc. common stockholders | $ (19,356) | $ (37,629) |
| Weighted average common stock outstanding used to compute net loss per share, basic and diluted | 434,158 | 960,882 |
| Net loss per share attributable to Silk Road Medical, Inc. common stockholders, basic and diluted | $ (44.58) | $ (39.16) |

The following potentially dilutive securities outstanding have been excluded from the computation of diluted weighted average shares outstanding because such securities have an antidilutive impact due to the Company's net loss, in common stock equivalent shares:

| | December 31, | |
|---|---|---|
| | 2017 | 2018 |
| Redeemable convertible preferred stock outstanding | 21,233,190 | 21,233,190 |
| Redeemable convertible preferred stock warrants outstanding | 2,672,502 | 2,672,502 |
| Common stock options | 4,308,890 | 4,364,377 |
| Common stock warrants outstanding | — | 7,527 |
| | 28,214,582 | 28,277,596 |

**Unaudited Pro Forma Net Loss per Share Attributable to Common Stockholders**

The unaudited pro forma basic and diluted net loss per share has been computed to give effect to the conversion of the shares of redeemable convertible preferred stock into common stock immediately prior to the closing of a qualifying IPO, following receipt of the requisite approval of preferred stockholders, as if such conversion had occurred at the beginning of the period, and the automatic net exercise of the redeemable convertible preferred and common stock warrants, as if such exercise had occurred at the beginning of the period or the issuance date, if later. In addition, the numerator in the pro forma basic and diluted net loss per share calculation has been adjusted to remove the change in the fair value resulting from the remeasurement of the redeemable convertible preferred stock warrant liability as the redeemable convertible preferred stock warrants will be automatically net exercised into common stock, and the related redeemable convertible preferred stock warrant liability will be reclassified to stockholders' deficit immediately prior to the closing of an IPO. The denominator in the pro forma basic and diluted net loss per share calculation has been adjusted to include (i) the conversion of all outstanding shares of redeemable convertible preferred stock and (ii) the number of shares into which the redeemable convertible preferred stock warrants and common stock warrants would be converted upon their net exercise immediately prior to the closing of an IPO, based on an initial public offering price of $20.00 per

share. The unaudited pro forma net loss per share does not include the shares to be sold and related proceeds to be received from an IPO.

Unaudited pro forma basic and diluted loss per share is computed as follows (in thousands, except share and per share data):

| | Year Ended December 31, 2018 (unaudited) |
|---|---|
| Numerator: | |
| Net loss and comprehensive loss attributable to Silk Road Medical, Inc. common stockholders | $ (37,629) |
| Adjust: Change in fair value of redeemable convertible preferred stock warrants | 11,906 |
| Pro forma net loss | $ (25,723) |
| Denominator: | |
| Weighted average common shares used to compute net loss per share, basic and diluted | 960,882 |
| Adjust: Conversion of redeemable convertible preferred stock | 21,233,190 |
| Adjust: Net exercise of redeemable convertible preferred stock warrants into common stock warrants | 1,856,046 |
| Adjust: Net exercise of common stock warrants into common stock | 181 |
| Weighted average common shares used to compute pro forma net loss per share, basic and diluted | 24,050,299 |
| Pro forma net loss per share, basic and diluted | $ (1.07) |

**Comprehensive Loss**

For the years ended December 31, 2017 and 2018, there was no difference between comprehensive loss and the Company's net loss.

**Segment and Geographical Information**

The Company operates and manages its business as one reportable and operating segment. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. All of the Company's long-lived assets are based in the United States. Long-lived assets are comprised of property and equipment. All of the Company's revenue was in the United States for the years ended December 31, 2017 and 2018, based on the shipping location of the external customer.

## 3. Recent Accounting Pronouncements

*Recently Adopted Accounting Standards*

In the first quarter of 2018, the Company adopted ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), and its associated amendments. Under the standard, revenue is recognized when a customer obtains control of promised goods or services in an amount that reflects the consideration the entity expects to receive in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The Company applied the five step method outlined in the ASU to all revenue streams and elected to utilize the modified retrospective implementation method. The

additional disclosures required by the ASU have been included in Note 2, "Summary of Significant Accounting Policies."

In the first quarter of 2018, the Company adopted ASU No. 2016-18, Statement of Cash Flows: Restricted Cash, a consensus of the Financial Accounting Standards Board (“FASB”) Emerging Issues Task Force. Under the standard, restricted cash and restricted cash equivalent amounts are presented within cash and cash equivalents when reconciling the total beginning and ending amounts shown on the statement of cash flows. When cash, cash equivalents, restricted cash and restricted cash equivalents are presented in more than one line item on the balance sheet, a reconciliation of the totals in the statement of cash flows to the related captions in the balance sheet is required. The impact of the adoption of ASU No. 2016-18 resulted in a decrease in investing activities of $310,000 and an increase in the ending cash, cash equivalents and restricted cash of $510,000 in the consolidated statement of cash flows for the year ended December 31, 2017. The impact of the adoption resulted in a decrease in investing activities and an increase in the ending cash, cash equivalents and restricted cash of $200,000 in the consolidated statement of cash flows for the year ended December 31, 2018.

In the first quarter of 2018, the Company adopted ASU No. 2017-09, Compensation - Stock Compensation - Scope of Modification Accounting. The standard provides clarification on when modification accounting should be used for changes to the terms or conditions of a share-based payment award. This standard does not change the accounting for modifications but clarifies that modification accounting guidance should only be applied if there is a change to the value, vesting conditions, or award classification and would not be required if the changes are considered non-substantive. The guidance was adopted on a prospective basis in the first quarter of 2018 and did not have any impact upon adoption.

In the first quarter of 2018, the Company adopted ASU No. 2018-07, Improvements to Nonemployee Share-Based Payment Accounting. ASU 2018-07 simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. Adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

*Recently Issued Accounting Standards*

In February 2016, the FASB issued ASU 2016-02, Leases (“ASC 842”), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases today. ASC 842 supersedes the previous leases standard, ASC 840, Leases. For public entities, the standard is effective for interim and annual periods beginning after December 15, 2018 and should be applied through a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with early adoption permitted. The Company plans to adopt the new standard on January 1, 2019 and elect the optional transition method. The Company will also elect the package of transitional practical expedients such that the Company will retain lease classification and initial direct costs for leases existing prior to the adoption of the new lease standard. The Company will also elect the hindsight practical expedient. Although the Company is currently evaluating the impact of this guidance on its consolidated financial statements, it does expect that most of its operating lease commitments will be subject to the new guidance and will be recognized as operating lease liabilities and right-of-use assets upon its adoption.

In June 2016, the FASB issued ASU 2016-13, Measurement of Credit Losses on Financial Statements. This update provides financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. The update replaces the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. ASU No. 2016-13 is effective for public entities for annual periods beginning after December 15, 2019. The Company does not believe that the adoption of this new guidance will have a material impact on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement, which changed the disclosure requirements for fair value measurements by removing, adding and modifying certain disclosures. The standard is effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company is evaluating the impact of adopting this guidance to its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-15, Cloud Computing Arrangements, which aligns the requirements for capitalizing implementation costs in a Cloud Computing Arrangement service contract with the requirements for capitalizing implementation costs incurred for an internal-use software license. The standard is effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company is evaluating the impact of adopting this guidance to its consolidated financial statements and related disclosures.

## 4. Fair Value Measurements

The Company measures certain financial assets and liabilities at fair value on a recurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. A three-tier fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value:

- Level 1 – quoted prices in active markets are identical assets and liabilities;
- Level 2 – observable inputs other than quotes prizes in active markets for identical assets and liabilities;
- Level 3 – unobservable inputs.

The Company's cash equivalents are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency.

In October and December 2015, the Company issued warrants to purchase 1,395,468 and 5,324 shares, respectively, of Series C redeemable convertible preferred stock at the exercise price of $6.11 per share. The Company recorded an initial warrant liability of $4,879,000. The redeemable convertible warrant liability was initially valued using the Black Scholes option-pricing valuation method with the following assumptions: a remaining contractual term of 8 years, a volatility of 52%, and a risk-free interest rate of 1.94% for the warrants issued in October, and a remaining contractual term of 8 years, a volatility of 52%, and a risk-free interest rate of 2.24% for the warrants issued in December. In April 2016, the Company issued additional warrants to purchase 42,608 shares of Series C redeemable convertible preferred stock at the exercise price of $6.11 per share. The Company recorded a warrant liability of $144,000. The redeemable convertible warrant liability was initially valued using the Black Scholes option-pricing valuation method with the following assumptions: a remaining contractual term of 7.5 years, a volatility of 50%, and a risk-free interest rate of 1.64%.

As a derivative liability, the redeemable convertible warrants were initially recorded at fair value and are subject to remeasurement at each balance sheet date. Any change in fair value as a result of a remeasurement is recognized as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss. The Company's redeemable convertible warrant liability is classified within Level 3 of the fair value hierarchy.

At December 31, 2017 and 2018, the fair value of the redeemable convertible warrant liability was determined by using an option pricing model to allocate the total enterprise value to the various securities within the Company's capital structure. The fair value of the redeemable convertible warrant liability was based on both the estimated fair value of the Company's common stock of $4.78 and $11.29 as of December 31, 2017 and 2018, respectively, and on valuation models discounted at current implied market rates which are based on Level 3 inputs. Additionally, the model's inputs reflect assumptions that market participants would use in pricing the instrument in a current period transaction and included:

| | Year Ended December 31, | |
|---|---|---|
| | 2017 | 2018 |
| Time to liquidity (years) | 1.75 | 0.57 |
| Expected volatility | 50.0% | 62.5% |
| Discounted cash flow rate | 18.0% | 12.0% |
| Risk-free interest rate | 1.9% | 2.6% |
| Marketability discount rate | 27% | 14% |

The following table sets forth the fair value of the Company's financial liabilities measured on a recurring basis, as of December 31, 2017 and 2018 (in thousands):

| | December 31, 2017 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| **Liabilities** | | | | |
| Redeemable convertible warrant liability | $ — | $ — | $ 4,185 | $ 4,185 |

| | December 31, 2018 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| **Liabilities** | | | | |
| Redeemable convertible warrant liability | $ — | $ — | $ 16,091 | $ 16,091 |

The changes in the redeemable convertible warrant liability are summarized below (in thousands):

| | |
|---|---|
| **Fair value at December 31, 2016** | $ 7,143 |
| Change in fair value recorded in other income (expense), net | (2,958) |
| **Fair value at December 31, 2017** | 4,185 |
| Change in fair value recorded in other income (expense), net | 11,906 |
| **Fair value at December 31, 2018** | $ 16,091 |

There were no transfers between fair value hierarchy levels during the years ended December 31, 2017 and 2018.

## 5. Balance Sheet Components

**Inventories**

| *(in thousands)* | December 31, 2017 | December 31, 2018 |
|---|---|---|
| Raw materials | $ 506 | $ 1,054 |
| Finished products | 2,742 | 4,690 |
| | $ 3,248 | $ 5,744 |

As of December 31, 2017 and 2018, there were no work-in-process inventories.

**Property and Equipment, Net**

| *(in thousands)* | December 31, 2017 | December 31, 2018 |
|---|---|---|
| Furniture and fixtures | $ 76 | $ 517 |
| Equipment | 1,059 | 1,217 |
| Software | 405 | 76 |
| Leasehold improvements | 189 | 1,978 |
| | 1,729 | 3,788 |
| Less: Accumulated depreciation and amortization | (1,303) | (946) |
| Add: Construction-in-progress | 60 | 38 |
| | $ 486 | $ 2,880 |

Depreciation and amortization expense was $129,000 and $517,000 for the years ended December 31, 2017 and 2018, respectively.

**Accrued Liabilities**

| *(in thousands)* | December 31, 2017 | December 31, 2018 |
|---|---|---|
| Accrued payroll and related expenses | $ 2,718 | $ 5,157 |
| Accrued professional services | 64 | 1,014 |
| Accrued royalty expense | — | 313 |
| Accrued travel expenses | 68 | 270 |
| Accrued clinical expenses | 183 | 244 |
| Accrued other expenses | 76 | 588 |
| | $ 3,109 | $ 7,586 |

## 6. Long-term Debt

In October 2015, the Company entered into a term loan agreement with CRG. The term loan agreement provides for up to $30,000,000 in term loans split into two tranches as follows: (i) the Tranche A Loans provided for $20,000,000 in term loans, and (ii) the Tranche B Loans provided for up to $10,000,000 in term loans. The Company drew down the Tranche A Loans on October 13, 2015. The Tranche B Loans

were available to be drawn prior to March 29, 2017. In January 2017, the term loan agreement was amended to extend the commitment period of the Tranche B Loans to April 28, 2017. In April 2017, the Company drew down $5,000,000 of the available Tranche B Loans.

In September 2018, the Company entered into Amendment No. 5 to the term loan agreement with CRG. Under the amended terms of the amended loan agreement the maturity date was extended to December 31, 2022 and the repayment schedule of the existing term loans were changed to interest only so that the outstanding principal amount of the term loans will be payable in a single installment at maturity. The related fixed interest rate was changed to equal 10.75% per annum, due and payable quarterly in arrears. At the election of the Company, 2.75% of the interest due and payable may be "paid in kind" and added to the then outstanding principal and 8.0% of the interest due and payable paid in cash. All unpaid principal, and accrued and unpaid interest, is due and payable in full on December 31, 2022. The amended term loan agreement also provided for additional term loans in an aggregate principal amount of up to $25,000,000 and allow for the conversion into shares of common stock, at the Company's option, of up to 25% of the outstanding loans under the term loan agreement in connection with an initial public offering of the Company's common stock which results in market capitalization of at least $250,000,000. In September 2018, the Company drew down an additional $15,000,000 under the term loan agreement with CRG.

The Company may voluntarily prepay the borrowings in full, with a prepayment premium beginning at 8.0% and declining to 4.0% after the fourth payment date, to 2.0% after the eighth payment date, with no premium being payable if prepayment occurs after the third year of the loan. The Tranche A borrowing required a payment, on the borrowing date, of a financing fee equal to 1.75% of the borrowed loan principal, which is recorded as a discount to the debt. In addition, a facility fee equal to 5.0% of the amounts borrowed plus any "paid in kind" is payable at the end of the term or when the borrowings are repaid in full. A long-term liability is being accreted using the effective interest method for the facility fee over the term of the loan agreement. The borrowings are collateralized by a security interest in substantially all of the Company's assets.

The Company is subject to financial covenants related to liquidity and minimum trailing revenue targets that begin in December 31, 2016 and are tested on an annual basis. The liquidity covenant requires the Company to maintain an amount which shall exceed the greater of (i) $3,000,000 and (ii) the minimum cash balance, if any, required of the Company by a creditor to the extent the Company has incurred permitted priority debt. The Company had to achieve minimum net revenue of $1,000,000 in 2016, $5,000,000 in 2017, $15,000,000 in 2018, and must achieve minimum net revenue of $30,000,000 in 2019 and $40,000,000 in 2020. The liquidity financial covenant has a 90-day equity cure period following end of the calendar year to issue additional shares of equity interests in exchange for cash, or to borrow permitted cure debt. In addition, the term loan agreement prohibits the payment of cash dividends on the Company's capital stock and also places restrictions on mergers, sales of assets, investments, incurrence of liens, incurrence of indebtedness and transactions with affiliates. CRG may accelerate the payment terms of the term loan agreement upon the occurrence of certain events of default set forth therein, which include the failure of the Company to make timely payments of amounts due under the term loan agreement, the failure of the Company to adhere to the covenants set forth in the term loan agreement, the insolvency of the Company or upon the occurrence of a material adverse change. As of December 31, 2018, the Company was in compliance with all applicable financial covenants. As of December 31, 2018, management does not believe that it is probable that the above clauses will be triggered within the next twelve months, and therefore, the debt is classified as long-term on the consolidated balance sheet.

The issuance costs and debt discount have been netted against the borrowed funds on the consolidated balance sheet. The long-term debt balance as of December 31, 2018 was $44,201,000.

Future maturities under the term loan agreement as of December 31, 2018 are as follows (in thousands):

| Year Ending December 31: | Amount |
|---|---|
| 2019 | $ 3,566 |
| 2020 | 3,677 |
| 2021 | 3,771 |
| 2022 | 52,510 |
| | 63,524 |
| Add: Accretion of closing fees | 872 |
| | 64,396 |
| Less: Amount representing interest | (20,010) |
| Less: Amount representing debt discount and debt issuance costs | (185) |
| Present value of minimum payments | $ 44,201 |

In October 2015, CRG purchased 327,759 shares of the Company's Series C redeemable convertible preferred stock at $6.11 per share. In addition, CRG received warrants to purchase 163,877 shares of the Company's Series C redeemable convertible preferred stock. The warrants are immediately exercisable, at an exercise price per share of $6.11, and expire the earlier of October 2023 or upon the consummation of a change of control or initial public offering of the Company.

In July 2017, CRG purchased 163,877 shares of the Company's Series C convertible preferred stock at $6.11 per share.

## 7. Commitments and Contingencies

**Operating Leases**

The Company's operating lease obligations primarily consist of leased office, laboratory, and manufacturing space under non-cancellable operating leases that expire in January 2019 and in October 2024. In November 2017, the Company entered into a six-year operating lease for new office space in Sunnyvale, the lease commenced in June 2018 and expires in October 2024. The lease agreement includes a renewal provision allowing the Company to extend this lease for an additional period of five years. In addition to the minimum future lease commitments presented below, the lease requires the Company to pay property taxes, insurance, maintenance, and repair costs. The lease includes a rent holiday concession and escalation clauses for increased rent over the lease term. Rent expense is recognized using the straight-line method over the term of the lease. The Company records deferred rent calculated as the difference between rent expense and the cash rental payments. In connection with the facility lease, the landlord provided incentives of $794,000 to the Company in the form of leasehold improvements. In addition, the landlord also provided for leasehold improvements financing of $316,000. The financing amount was added to the Company's minimum lease commitments as of the lease commencement date at an interest rate of 7.0% per annum. These amounts have been reflected as deferred rent and are being amortized as a reduction to rent expense over the original term of the Company's operating lease.

The aggregate future minimum lease payments as of December 31, 2018 are as follows (in thousands):

| Year Ending December 31: | Total Minimum Lease Payments |
|---|---|
| 2019 | $ 1,002 |
| 2020 | 1,002 |
| 2021 | 1,031 |
| 2022 | 1,044 |
| 2023 and thereafter | 1,920 |
| | $ 5,999 |

**Purchase Obligations**

Purchase obligations consist of agreements to purchase goods and services entered into in the ordinary course of business. The Company had non-cancellable commitments for inventory that were payable within one year to suppliers for purchases totaling $4,648,000 as of December 31, 2018.

**Indemnification**

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and may provide for indemnification of the counterparty. The Company's exposure under these agreements is unknown because it involves claims that may be made against it in the future but have not yet been made. To date, the Company has not been subject to any claims or been required to defend any action related to its indemnification obligations.

The Company indemnifies each of its directors and officers for certain events or occurrences, subject to certain limits, while the director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of incorporation and bylaws. The term of the indemnification period lasts as long as a director may be subject to any proceeding arising out of acts or omissions of such director in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director liability insurance. This insurance allows the transfer of risk associated with the Company's exposure and may enable it to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations as of December 31, 2018.

**Legal Proceedings**

The Company is not involved in any pending legal proceedings that it believes could have a material adverse effect on its financial condition, results of operations or cash flows. From time to time, the Company may pursue litigation to assert its legal right and such litigation may be costly and divert the efforts and attention of its management and technical personnel which could adversely affect its business.

## 8. Redeemable Convertible Preferred Stock

The Company has the following redeemable convertible preferred stock issued and outstanding at December 31, 2017 and 2018:

| | December 31, 2017 and 2018 | | | | |
|---|---|---|---|---|---|
| | Shares Authorized | Shares Issued and Outstanding | Per share Preference | Preferential Liquidation Value (in thousands) | Carrying Value (in thousands) |
| **Series** | | | | | |
| Series A | 1,629,629 | 1,629,626 | $ 2.70 | $ 4,400 | $ 4,369 |
| Series A-1 | 1,111,111 | 1,111,109 | $ 3.38 | 3,755 | 3,723 |
| Series B | 6,264,470 | 6,264,463 | $ 6.11 | 38,276 | 38,014 |
| Series C | 15,064,405 | 12,227,992 | $ 6.11 | 74,713 | 59,129 |
| | 24,069,615 | 21,233,190 | | $ 121,144 | $ 105,235 |

As of December 31, 2017 and 2018, the holders of redeemable convertible preferred stock ("convertible preferred stock") have various rights and preferences as follows:

**Voting Rights**

The holders of Series A, Series A-1, Series B and Series C convertible preferred stock are entitled to vote on all matters on which the common stockholders are entitled to vote. Holders of Series A, Series A-1, Series B and Series C convertible preferred and common stock vote together as a single class. Each holder of Series A, Series A-1, Series B and Series C convertible preferred stock is entitled to the number of votes equal to the number of common stock shares into which the shares held by such holder are convertible.

**Election of Directors**

The holders of record of Series A and Series B preferred stock, exclusively and as a separate class, are entitled to each elect two and three directors of the Company, and the holders of record of Series C preferred stock, exclusively and as a separate class, are entitled to elect two directors of the Company.

**Dividends**

The holders of Series A, Series A-1, Series B and Series C convertible preferred stock are entitled, on a pari passu basis, when and if declared by the Board of Directors of the Company, to non-cumulative dividends out of the Company's assets legally available therefore at the rate of $0.22, $0.27, $0.49 and $0.49 per share per annum, respectively. No distributions will be made with respect to the common stock until all declared but unpaid dividends on convertible preferred stock have been paid or set aside for payment to the convertible preferred stock holders. The right to receive dividends on shares of convertible preferred stock will be non-cumulative, and no right to such dividends will accrue to holders of convertible preferred stock by reason of the fact that dividends on such shares are not declared or paid in any years. As of December 31, 2018, no dividends have been declared to date.

**Liquidation**

In the event of any liquidation, dissolution or winding up of the Company, either voluntary or involuntary, the holders of Series C preferred stock will be entitled to receive out of net available funds and assets of the corporation available for distribution to its stockholders, before any payment shall be made to the

holders of Series B preferred stock and Series A preferred stock and Series A-1 junior stock. After the payment of all preferential amounts required to be paid to the holders of Series C preferred stock, the holders of Series B, Series A and Series A-1 outstanding shares of convertible preferred stock will be entitled to receive out of net available funds and assets, before and in preference to any distribution of any of the Company's net available funds and assets to the holders of common stock by reason of their ownership of such common stock.

An amount per share equal to $6.11, $6.11, $3.38 and $2.70 for each share of Series C, Series B, Series A-1 and Series A, respectively, convertible preferred stock then so held equal to the applicable liquidation preference. The remaining assets, if any, shall be distributed to the holders of common stock. Should the Company's legally available assets be insufficient to satisfy the liquidation preferences after the payment of all preferential amounts required to be paid to the holders of Series C preferred stock, the funds will be distributed ratably among the holders of Series A, Series A-1, and Series B convertible preferred stock in proportion to the preferential amount each holder is otherwise entitled to receive.

**Conversion**

Shares of convertible preferred stock are convertible into shares of common stock at the holders' option at any time or automatically (i) immediately prior to the closing of a firmly underwritten public offering in which the offering price per share is not less than $18.31 and the aggregate gross proceeds received by the Company are not less than $50,000,000 or (ii) upon receipt by the Company of a written request for such conversion from the holders of the majority of the convertible preferred stock then outstanding, voting as a single class and on an as-converted basis. Each share of Series A, Series A-1, Series B and Series C convertible preferred stock is convertible, at the option of the holder, into the number of shares of common stock into which such shares are convertible at the then effective conversion ratio. The initial conversion price per share for Series A, Series A-1, Series B and Series C convertible preferred stock is $2.70, $3.38, $6.11 and $6.11 per share, respectively. The initial conversion price is subject to adjustment from time to time. As of December 31, 2018, the conversion ratio for each series of convertible preferred stock was one-for-one.

**Redemption**

The redeemable convertible preferred stock is recorded in mezzanine equity because while it is not mandatorily redeemable, it will become redeemable at the option of the stockholders upon the occurrence of certain deemed liquidation events that are considered not solely within the Company's control.

**Preferred Stock Warrants**

In connection with the issuance of the Company's Series C redeemable convertible preferred stock issuances between August 2014 through April 2016, the Company issued, to each investor who purchased shares of Series C redeemable convertible preferred stock, warrants to purchase up to the number of shares of preferred stock equal to 50% of the number of shares of the Company's Series C redeemable convertible preferred stock purchased.

The warrants are immediately exercisable, at an exercise price per share of $6.11 and expire eight years from their date of issuance. The warrants will be automatically net exercised upon the consummation or effective date of a change of control or initial public offering of the Company.

As of December 31, 2017 and 2018, warrants to purchase an aggregate of 2,672,502 shares of Series C redeemable convertible preferred stock were outstanding.

## 9. Common Stock

At December 31, 2018, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 29,879,220 shares of common stock with $0.001 par value per share, of which 1,135,310 shares were issued and outstanding. The holders of common stock are also entitled to receive dividends whenever funds are legally available, when and if declared by the Board of Directors. As of December 31, 2018, no dividends have been declared to date. Each share of common stock is entitled to one vote.

At December 31, 2017 and 2018, the Company had reserved common stock for future issuances as follows:

| | December 31, | |
|---|---|---|
| | 2017 | 2018 |
| Conversion of Series A convertible preferred stock | 1,629,629 | 1,629,629 |
| Conversion of Series A-1 convertible preferred stock | 1,111,111 | 1,111,111 |
| Conversion of Series B convertible preferred stock | 6,264,470 | 6,264,470 |
| Conversion of Series C convertible preferred stock and warrants | 15,064,405 | 15,064,405 |
| Exercise of options under stock plan | 4,308,890 | 4,364,377 |
| Issuance of options under stock plan | 328,290 | 57,889 |
| Warrants to purchase common stock | — | 7,527 |
| | 28,706,795 | 28,499,408 |

**Common Stock Warrants**

In connection with the Company's acquisition of NeuroCo in December 2018, as of the merger closing, the outstanding warrants to purchase common stock of NeuroCo converted to warrants to purchase 7,527 shares of the Company's common stock.

The warrants are exercisable, at an exercise price per share of $8.27 and expire on November 21, 2024. The warrants will be automatically net exercised upon the consummation or effective date of a change of control or initial public offering of the Company.

As of December 31, 2018, warrants to purchase an aggregate of 7,527 shares of common stock were outstanding.

## 10. Stock Option Plan

In 2007, the Company established its 2007 Stock Option Plan (the "Plan") which provides for the granting of stock options to employees, directors and consultants of the Company. Options granted under the Plan may be either incentive stock options ("ISOs") or nonqualified stock options ("NSOs"). ISOs may be granted only to Company employees (including officers and directors who are also employees). NSOs may be granted to Company employees, directors and consultants. As of December 31, 2018, the Company has reserved 5,488,229 shares of common stock for issuance under the Plan.

In connection with its acquisition of NeuroCo in December 2018, the Company also assumed NeuroCo's 2015 Equity Incentive Plan, or the NeuroCo Plan. As of the merger closing, the outstanding options to purchase common stock of NeuroCo under the NeuroCo Plan converted to options to purchase 1,442 shares of the Company's common stock. There are no additional shares of common stock reserved for issuance under the NeuroCo Plan.

The exercise price of ISOs and NSOs shall not be less than 100% and 85% of the estimated fair value of the shares on the date of grant, respectively, as determined by the Board of Directors. The exercise price of ISOs and NSOs granted to a 10% stockholder shall not be less than 110% of the estimated fair value of the shares on the date of grant as determined by the Board of Directors. To date, options have a term of ten years and generally vest over 4 years with 25% vesting on the first anniversary of the issuance date, and then monthly vesting for an additional three years from date of grant.

Activity under the Company's Plan and the NeuroCo Plan is set forth below:

| | | Options Outstanding | | | |
|---|---|---|---|---|---|
| | Shares Available for Grant | Number of Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (in Years) | Aggregate Intrinsic Value (in thousands) |
| **Balances, December 31, 2016** | 27,605 | 3,478,346 | $ 1.46 | 7.71 | $ 444 |
| Authorized | 1,421,867 | | | | |
| Options granted | (1,375,329) | 1,375,329 | $ 6.54 | | |
| Options exercised | — | (290,638) | $ 1.17 | | |
| Options cancelled | 254,147 | (254,147) | $ 1.55 | | |
| **Balances, December 31, 2017** | 328,290 | 4,308,890 | $ 3.09 | 7.81 | $ 5,073 |
| Authorized | 223,664 | | | | |
| Options granted | (629,716) | 629,716 | $ 6.51 | | |
| Options exercised | — | (438,578) | $ 1.50 | | |
| Options cancelled | 135,651 | (135,651) | $ 1.56 | | |
| **Balances, December 31, 2018** | 57,889 | 4,364,377 | $ 3.79 | 7.36 | $ 33,132 |
| Vested and exercisable at December 31, 2018 | | 2,459,116 | $ 2.35 | 6.28 | $ 22,109 |
| Vested and expected to vest at December 31, 2018 | | 4,464,377 | $ 3.79 | 7.36 | $ 33,132 |

The following table summarizes information about stock options outstanding at December 31, 2018:

| | Options Outstanding and Vested as of December 31, 2018 | | | | |
|---|---|---|---|---|---|
| | Options Outstanding | | | Options Vested | |
| Exercise Price | Options Outstanding | Weighted Average Remaining Contractual Term (in Years) | Weighted Average Exercise Price | Number Exercisable | Weighted Average Exercise Price |
| $0.68 | 101,848 | 1.59 | $ 0.68 | 101,848 | $ 0.68 |
| $1.35 | 107,938 | 2.75 | $ 1.35 | 107,938 | $ 1.35 |
| $1.38 | 304,396 | 3.96 | $ 1.38 | 304,396 | $ 1.38 |
| $1.46 | 385,070 | 6.21 | $ 1.46 | 360,470 | $ 1.46 |
| $1.57 | 97,311 | 8.07 | $ 1.57 | 42,013 | $ 1.57 |
| $1.60 | 1,463,632 | 6.82 | $ 1.60 | 1,128,569 | $ 1.60 |
| $3.16 | 462,764 | 8.95 | $ 3.16 | 162,549 | $ 3.16 |
| $4.73 | 332,385 | 8.92 | $ 4.73 | 86,506 | $ 4.73 |
| $6.11 | 552,462 | 9.32 | $ 6.11 | 29,848 | $ 6.11 |
| $8.27 | 78,941 | 9.93 | $ 8.27 | 1,527 | $ 8.27 |
| $12.15 | 477,630 | 8.92 | $ 12.15 | 133,452 | $ 12.15 |
| | 4,364,377 | 7.36 | $ 3.79 | 2,459,116 | $ 2.35 |

**Stock-Based Compensation Associated with Awards to Employees**

During the years ended December 31, 2017 and 2018, the Company granted stock options to employees to purchase 1,371,626 and 575,314 shares of common stock, with a weighted-average grant date fair value of $0.83 and $2.81 per share, respectively. The total fair value of options vested during the years ended December 31, 2017 and 2018 was $423,000 and $569,000, respectively. The aggregate intrinsic value of options exercised was $143,000 and $787,000 during the years ended December 31, 2017 and 2018, respectively. The aggregate intrinsic value was calculated as the difference between the exercise prices of the underlying options and the estimated fair value of the common stock on the date of exercise. Stock-based compensation expense recognized during the years ended December 31, 2017 and 2018 includes compensation expense for stock–based awards granted to employees based on the grant date fair value of $442,000 and $728,000, respectively.

The Company also issues stock options with vesting based upon completion of performance goals. The fair value for these performance-based awards is recognized over the period during which the goals are to be achieved. Stock-based compensation expense recognized at fair value includes the impact of estimated probability that the goals would be achieved, which is assessed prior to the requisite service period for the specific goals.

The Company estimated the fair value of stock options using the Black–Scholes option pricing model. The fair value of employee stock options is being amortized on a straight–line basis over the requisite service period of the awards. The fair value of employee stock options was estimated using the following assumptions for the years ended December 31, 2017 and 2018:

| | Year Ended December 31, | |
|---|---|---|
| | 2017 | 2018 |
| Expected term (in years) | 1.00 - 6.25 | 6.25 |
| Expected volatility | 39% - 41% | 38.1% - 38.8% |
| Risk-free interest rate | 1.03% - 2.25% | 2.68% - 2.98% |
| Dividend yield | —% | —% |

The fair value of common stock was determined by the Company's Board of Directors, who considered, among other things, contemporaneous valuations of the Company's common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. The expected term of stock options represents the weighted-average period the stock options are expected to remain outstanding. The Company does not have sufficient historical exercise and post-vesting termination activity to provide accurate data for estimating the expected term of options and has opted to use the "simplified method," whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option. The expected stock price volatility assumption was determined by examining the historical volatilities for industry peers, as the Company did not have any trading history for the Company's common stock. The Company will continue to analyze the historical stock price volatility and expected term assumption as more historical data for the Company's common stock becomes available. The risk-free interest rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of the Company's stock options. The expected dividend assumption is based on the Company's history and expectation of dividend payouts.

Effective January 1, 2018, the Company made an accounting policy election to account for forfeitures as they occur.

**Stock-Based Compensation Associated with Awards to Nonemployees**

During the years ended December 31, 2017 and 2018, the Company granted options to purchase 3,703 and 52,960 shares, respectively, of common stock to consultants in exchange for services. Stock–based compensation expense related to stock options granted to nonemployees is recognized as the stock options are earned.

The fair value of stock options granted to nonemployees was calculated using the following assumptions:

| | Year Ended December 31, | |
|---|---|---|
| | 2017 | 2018 |
| Contractual term (in years) | 3.75 - 9.75 | 5.00 - 6.25 |
| Expected volatility | 39% - 56% | 38.0% - 38.8% |
| Risk-free interest rate | 2.06% - 2.39% | 2.71% - 2.90% |
| Dividend yield | —% | —% |

In connection with the grant of stock options to nonemployees, the Company recorded stock–based compensation charges of $93,000 and $183,000 for the years ended December 31, 2017 and 2018, respectively.

Total stock-based compensation expense relating to the Company's stock options to employees and nonemployees during the years ended December 31, 2017 and 2018, is as follows (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2017 | 2018 |
| Cost of goods sold | $ 49 | $ 51 |
| Research and development expenses | 98 | 256 |
| Selling, general and administrative expenses | 388 | 604 |
| | $ 535 | $ 911 |

As of December 31, 2018, there was total unrecognized compensation costs of $2,524,000 related to these stock options. These costs are expected to be recognized over a period of approximately 3.47 years.

## 11. Income Taxes

The Company uses the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company must then assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to the Company's lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance.

The Company recognizes benefits of uncertain tax positions if it is more likely than not that such positions will be sustained upon examination based solely on their technical merits, as the largest amount of benefit that is more likely than not to be realized upon the ultimate settlement. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

The components of income before taxes are as follows (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2017 | 2018 |
| United States | $ (22,358) | $ (37,630) |
| International | — | — |
| | $ (22,358) | $ (37,630) |

A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate is as follows (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2017 | 2018 |
| Tax at federal statutory rate | $ (7,602) | $ (7,902) |
| State taxes, net of federal benefit | (1,155) | (1,582) |
| Permanent differences | 535 | 289 |
| Loss on Series C warrant liability | — | 2,500 |
| Tax Cut and Jobs Act | 12,456 | — |
| Change in valuation allowance | (3,832) | 6,197 |
| General business credits | (465) | 136 |
| Other | 69 | 376 |
| Provision for taxes | $ 6 | $ 14 |

Significant components of the Company's net deferred tax assets as of December 31, 2017 and 2018 consist of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2017 | 2018 |
| Deferred tax assets: | | |
| Net operating loss carryforwards | $ 28,056 | $ 33,815 |
| Research and development credits | 5,081 | 4,944 |
| Capitalized start-up costs/Intangibles | 19 | 16 |
| Accruals and reserves | 705 | 1,169 |
| Property and equipment | 44 | 82 |
| Stock-based compensation | 197 | 274 |
| Total deferred tax assets | 34,102 | 40,300 |
| Less: Valuation allowance | (34,102) | (40,300) |
| Net deferred tax assets | $ — | $ — |

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management believes it is more likely than not that the deferred tax assets will not be realized; accordingly, a valuation allowance has been established on U.S. net deferred tax assets. The valuation allowance decreased $3,832,000 during the year ended December 31, 2017 and increased by $6,197,000 during the year ended December 31, 2018.

As of December 31, 2018, the Company had net operating loss carryforwards of approximately $125,187,000 and $115,827,000 for federal and state income tax purposes, respectively. The federal and state net operating loss carryforwards begin to expire in 2027 and 2028, respectively.

The federal and state net operating loss carryforwards may be subject to significant limitations under Section 382 and Section 383 of the Internal Revenue Code and similar provisions under state law. The Tax Reform Act contains provisions that limit the federal net operating loss carryforwards that may be used in any given year in the event of special occurrences, including significant ownership changes. A

Section 382 "ownership change" generally occurs if one or more stockholders or groups of stockholders, who own at least 5% of the Company's stock, increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. The Company may have previously experienced, and may in the future experience, one or more Section 382 "ownership changes," including in connection with the Company's initial public offering. If so, the Company may lose some or all of the tax benefits of its NOLs and tax credits. The extent of such limitations for prior years, if any, has not yet been determined.

At December 31, 2018, the Company had $4,083,000 and $2,655,000 of federal research and development tax credits and state tax credits, respectively. The state tax credits are made up of California Research and Development Credits and California New Jobs Credits. If not utilized, the Federal credits will expire beginning in 2027. The California Research and Development credits can be carried forward indefinitely, while the California New Jobs Credits begin to expire in 2019.

As of December 31, 2018, the Company had $1,348,000 of unrecognized tax benefits. The Company does not have any tax positions for which it is reasonably possible that the total amount of gross unrecognized would increase or decrease within twelve months of the year ended December 31, 2018. If recognized, $0 would affect the effective tax rate.

The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. There was no such expense recorded during the years ended December 31, 2017 and 2018.

A reconciliation of the unrecognized tax benefits from January 1, 2017 to December 31, 2018 is as follows (in thousands):

| | December 31, | |
|---|---|---|
| | 2017 | 2018 |
| Balance at the beginning of year | $ 551 | $ 615 |
| Increases related to current years' tax positions | 64 | 118 |
| Increases/(decreases) related to prior years' tax positions | — | 615 |
| Balance at end of year | $ 615 | $ 1,348 |

The Company currently has no federal or state tax examinations in progress nor has it had any federal or state tax examinations since its inception. As a result of the Company's net operating loss carryforwards, all of its tax years are subject to federal and state tax examination.

On December 22, 2017, the United States enacted a law commonly known as the Tax Cuts and Jobs Act (“TCJA” or “Act”) which makes widespread changes to the Internal Revenue Code, including a reduction in the federal corporate tax rate to 21%, effective January 1, 2018. The Company is subject to the provisions of FASB ASC 740-10, which requires that the effect on deferred tax assets and liabilities of a change in tax rates be recognized in the period the tax rate change was enacted. Consequently, the reduction in the U.S. corporate income tax rate as a result of the TCJA impacts the carrying value of deferred tax assets.

In response to the Tax Act, the SEC staff issued guidance on accounting for the tax effects of the Tax Act. The guidance provided a one-year measurement period for companies to complete the accounting. During the year ended December 31, 2017, the Company completed its accounting for the income tax effects of the Tax Act.

## 12. Acquisition of Variable Interest Entity - NeuroCo

In December 2014, the Board of Directors of the Company approved the sale of certain intellectual property of Silk Road Medical, Inc., to a newly incorporated entity, NeuroCo, Inc. In consideration for the intellectual property, a promissory note was executed between the two parties for the principal sum of $498,000 with an interest rate of 2.74% per annum, payable on the earlier of 10 years from the date of promissory note, or upon the occurrence of an event of default. The intellectual property transfer was recorded at its carrying value of zero as of December 31, 2014. During 2015 NeuroCo issued $154,000 in common stock to stockholders of the Company. During the years ended December 31, 2017 and 2018, NeuroCo issued common stock upon the exercise of stock options. These common stock issuance amounts, as they are related to non-controlling investors, were reported as non-controlling interests in subsidiary in the Company's consolidated financial statements and are offset by NeuroCo losses consolidated by the Company.

Additionally, NeuroCo incurred Research and Development related expenses paid for by the Company which were added in to the original promissory note. As of December 31, 2017, the promissory note amount was $1,544,000.

The Company had identified NeuroCo as a VIE of which the Company is the primary beneficiary. Pursuant to the accounting guidance for consolidating VIEs the main consideration was given to the fact that the amount of total equity investment at risk is not sufficient to permit NeuroCo to finance its activities without additional subordinated financial support. Additionally, NeuroCo and Silk Road Medical have the same Board of Directors and senior management composition, determining the Company to have the power to direct the activities that most significantly impact NeuroCo's economic performance and the obligation to absorb losses and the right to receive benefits. Accordingly, the financial results of NeuroCo were included in the Company's consolidated financial statements.

On December 17, 2018, the Company and NeuroCo entered into the Agreement and Plan of Merger (the "Merger Agreement") pursuant to which the Company acquired all assets and assumed all liabilities of NeuroCo (the "Merger"). The Merger closed on the same day (the "Closing") and was consummated through a stock-for-stock transaction based on the relative values of the Company's and NeuroCo's equity. In consideration for 100% equity interest of NeuroCo, the Company issued 33,462 shares of its common stock and the above promissory note in the amount of approximately $1,600,000 as of the Closing was settled and canceled. As a result of the Merger, NeuroCo merged into the Company with the Company being the surviving corporation.

As the Company already controlled and consolidated NeuroCo and retained the control over NeuroCo's business after the Merger, the Company accounted for the acquisition of equity interest in NeuroCo as an equity transaction. Therefore, the Company did not recognize a gain or loss in its consolidated net loss or comprehensive loss for acquisition of NeuroCo. As the carrying amount of the non-controlling interest as of the Closing was zero, the Company recorded the consideration paid as a decrease to the Company's additional paid-in capital within stockholder's deficit.

As part of the Merger, the Company assumed NeuroCo's 2015 Equity Incentive Plan (the "NeuroCo Plan") along with all of NeuroCo's rights and obligations under the NeuroCo Plan, except that the number of shares and exercise price of the assumed options have been adjusted based on the Merger exchange ratio of the Company's common stock and NeuroCo's common stock. Similarly, the Company assumed outstanding warrants to purchase NeuroCo's common stock such that the number of shares and exercise price of the assumed warrants have been adjusted based on the Merger exchange ratio of the Company's common stock and NeuroCo's common stock. The options and warrants to purchase shares of the Company's common stock were fully vested upon issuance, as they were replacing fully vested options and warrants to purchase NeuroCo common stock.

## 13. 401(k) Plan

The Company has a qualified retirement plan under section 401(k) of the Internal Revenue Code ("IRC") under which participants may contribute up to 90% of their eligible compensation, subject to maximum deferral limits specified by the IRC. The Company may make a discretionary matching contribution to the 401(k) plan and may make a discretionary employer contribution to each eligible employee each year. To date, the Company has made no contributions to the 401(k) plan.

## 14. Subsequent Events

The Company has evaluated subsequent events through March 1, 2019, which is the date these audited consolidated financial statements were available for issuance. The Company has also evaluated subsequent events through March 27, 2019 for the effects of the reverse stock split described in Note 1.

**Contingencies**

In February 2019, a former employee, through counsel, advised the Company that he had filed a charge of discrimination against the Company with the California Department of Fair Employment & Housing, or DFEH. The former employee's complaint alleges sexual harassment and retaliation in violation of the California Department of Fair Employment & Housing Act. The complaint does not allege specific damages. To date, the DFEH has not contacted the Company. The Company denies the complaint's allegations and intends to vigorously defend itself. At this time the Company cannot estimate the outcomes or possible loss or range of loss arising from this claim**,** if any**;** as such, no accrual was included in the Company's balance sheet as of December 31, 2018.

**2007 Stock Option Plan**

In February 2019, the Company's Board of Directors approved the grant of options to purchase 32,950 shares of common stock under the 2007 Stock Option Plan at an exercise price of $11.29 per share. These stock options have a grant date fair value of approximately $160,000 that is expected to be recognized over a requisite service period of four years.

## 15. Events Subsequent to Original Issuance of Consolidated Financial Statements (unaudited)

The Company has evaluated subsequent events after March 1, 2019 through April 2, 2019.

**Amended and Restated Certificate of Incorporation**

In March 2019, the Company's Board of Directors approved that immediately prior to the consummation of the Company's IPO, the Company will file an amended and restated certificate of incorporation that authorizes 100,000,000 shares of common stock, $0.001 par value per share, and 5,000,000 shares of preferred stock, $0.001 par value per share.

**2007 Stock Plan**

In March 2019, the Company's Board of Directors approved the termination of the 2007 Stock Plan effective immediately prior to consummation of the Company's IPO.

**NeuroCo 2015 Equity Incentive Plan**

In March 2019, the Company's Board of Directors approved the termination of the NeuroCo 2015 Equity Incentive Plan effective immediately prior to consummation of the Company's IPO.

**2019 Equity Incentive Plan**

In March 2019, the Company's Board of Directors adopted the 2019 Equity Incentive Plan ("2019 Plan"). The 2019 Plan provides for the grant of ISOs to employees and for the grant of NSOs, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to employees, directors and consultants. A total of 2,317,000 shares of common stock were reserved for issuance pursuant to the 2019 Plan. In addition, the shares reserved for issuance under the 2019 Plan will also include shares reserved but not issued under the 2019 Plan, plus any share awards granted under the 2007 Plan that expire or terminate without having been exercised in full or that are forfeited or repurchased. In addition, the number of shares available for issuance under the 2019 Plan will also include an annual increase on the first day of each fiscal year beginning in fiscal 2020, equal to the lesser of (i) 3,000,000 shares; (ii) 4.0% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (iii) an amount as determined by the Board of Directors.

On March 21, 2019, the Company’s Board of Directors approved the grant of options to purchase 654,792 shares of common stock under the 2019 Equity Incentive Plan, with a grant date of the effective date of the Company’s registration statement on Form S-1 for its IPO with an exercise price equal to the initial public offering price.

**2019 Employee Stock Purchase Plan**

In March 2019, the Company's Board of Directors adopted the 2019 Employee Stock Purchase Plan ("ESPP") under which eligible employees are permitted to purchase common stock at a discount through payroll deductions. A total of 434,000 shares of common stock are reserved for issuance and will be increased on the first day of each fiscal year, beginning in 2019, by an amount equal to the lesser of (i) 1,200,000 shares (ii) 1.0% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (iii) an amount as determined by the Board of Directors. The price of the common stock purchased will be the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. The ESPP was effective upon adoption by the Company's Board of Directors but will not be in use until the completion of the IPO. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended.

*6,000,000 Shares*


*Common Stock*

# Prospectus

**J.P. Morgan** **BofA Merrill Lynch**

**BMO Capital Markets** **Stifel**

April 3, 2019